

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

## High Pure PCR Template Preparation Kit

Version  
1.3

Revision Date:  
03.04.2024

Date of last issue: 03.04.2024  
Date of first issue: 27.01.2023

### Cover letter for product:

Trade name : High Pure PCR Template Preparation Kit  
Product code : 11796828001

The product is sold as a kit, and contains the following components:

- 1) Tissue Lysis Buffer
- 2) Proteinase K, PCR grade
- 3) Wash Buffer I / Inhibitor Removal Buffer
- 4) Wash buffer
- 5) Elution Buffer
- 6) Binding buffer, universal MBF

The following is an overview of the labeling elements of the kit:

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

Hazard pictograms :



Signal word : Danger

Hazard statements : H302 + H332 Harmful if swallowed or if inhaled.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H335 May cause respiratory irritation.

Precautionary statements : **Prevention:**  
P261 Avoid breathing dust.  
P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves/ eye protection/ face protection.

#### **Response:**

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

#### **Additional Labelling**

EUH210 Safety data sheet available on request.

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**The product was evaluated per International Air Transport Association (IATA) specifications with the following outcome:**

Not assigned by regulation

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

#### 1.1 Product identifier

Trade name : Tissue Lysis Buffer

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

Use of the Substance/Mixture : Laboratory chemicals, Refer to product literature for further details.

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
Sandhoferstrasse 116  
68305 Mannheim  
Germany

Telephone : +496217590  
Telefax : +496217592890  
Responsible Department :  
E-mail address : info.dia-sds@roche.com

#### 1.4 Emergency telephone number

In case of emergencies: : CHEMTREC 0800-181-7059/  
+(49)-69643508409

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

Not a hazardous substance or mixture.

#### 2.2 Label elements

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

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

##### Additional Labelling

EUH210 Safety data sheet available on request.

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

#### 3.2 Mixtures

##### Components

| Chemical name  | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification  | Concentration<br>(% w/w) |
|--|---|---|--------------------------|
| Ethylenediaminetetraacetic acid<br>disodium salt dihydrate | 6381-92-6<br><br>01-2119486775-20                     | Acute Tox. 4; H332<br>STOT RE 2; H373<br>(Respiratory system) | >= 1,0 - < 10,0          |

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

None known.

#### 4.3 Indication of any immediate medical attention and special treatment needed

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

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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

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

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : No information available.

Hazardous combustion products : Nitrogen oxides (NO<sub>x</sub>)  
Carbon oxides

#### 5.3 Advice for firefighters

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

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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### SECTION 6: Accidental release measures

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

Personal precautions : Refer to protective measures listed in sections 7 and 8.

#### 6.2 Environmental precautions

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

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

#### 6.4 Reference to other sections

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

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

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### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Electrical installations / working materials must comply with the technological safety standards.

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

Advice on common storage : No materials to be especially mentioned.

Storage class (TRGS 510) : 12

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

#### Occupational Exposure Limits

| Components  | CAS-No.   | Value type (Form of exposure) | Control parameters    | Basis                                     |
|---|-----------|-------------------------------|-----------------------|---|
| Ethylenediaminetetraacetic acid disodium salt dihydrate<br>The value is given in analogy to the following substances: edetic acid | 6381-92-6 | IOEL                          | 1,5 mg/m <sup>3</sup> | Roche Industrial Hygiene Committee (RIHC) |

### 8.2 Exposure controls

#### Engineering measures

No data available

#### Personal protective equipment

Eye/face protection : Safety glasses

Hand protection

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,

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

Skin and body protection : Protective suit

Respiratory protection : No personal respiratory protective equipment normally required.

### SECTION 9: Physical and chemical properties

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

Physical state : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

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

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : 7,4

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

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Vapour pressure : No data available  
Relative density : No data available  
Relative vapour density : No data available  
Particle characteristics  
Particle Size Distribution : Not applicable

### 9.2 Other information

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

## 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 : No dangerous reaction known under conditions of normal use.  
Stable under recommended storage conditions.  
No hazards to be specially mentioned.

### 10.4 Conditions to avoid

Conditions to avoid : No data available

### 10.5 Incompatible materials

Materials to avoid : No data available

### 10.6 Hazardous decomposition products

No data available



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### SECTION 11: Toxicological information

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

##### Acute toxicity

Not classified due to lack of data.

##### Product:

Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: Calculation method

##### Components:

##### **Ethylenediaminetetraacetic acid disodium salt dihydrate:**

Acute oral toxicity : LD50 Oral (Rat, male and female): 2.800 mg/kg  
Method: OECD Test Guideline 401  
Test substance: anhydrous substance  
GLP: no

Acute inhalation toxicity : Lowest Observed Effect Concentration: ca. 0,03 mg/l  
Exposure time: 6 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 412  
GLP: yes  
Assessment: The component/mixture is moderately toxic after short term inhalation.

##### Skin corrosion/irritation

Not classified due to lack of data.

##### Components:

##### **Ethylenediaminetetraacetic acid disodium salt dihydrate:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

##### Serious eye damage/eye irritation

Not classified due to lack of data.

##### Components:

##### **Ethylenediaminetetraacetic acid disodium salt dihydrate:**

Species : Rabbit  
Result : No eye irritation  
Test substance : anhydrous substance  
Remarks : Based on data from similar materials

##### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified due to lack of data.

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### Respiratory sensitisation

Not classified due to lack of data.

#### Components:

##### Ethylenediaminetetraacetic acid disodium salt dihydrate:

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

### Germ cell mutagenicity

Not classified due to lack of data.

#### Components:

##### Ethylenediaminetetraacetic acid disodium salt dihydrate:

Genotoxicity in vitro : Test Type: Ames test  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: no

### Carcinogenicity

Not classified due to lack of data.

### Reproductive toxicity

Not classified due to lack of data.

### STOT - single exposure

Not classified due to lack of data.

### STOT - repeated exposure

Not classified due to lack of data.

#### Components:

##### Ethylenediaminetetraacetic acid disodium salt dihydrate:

Exposure routes : Inhalation  
Target Organs : Respiratory system  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### Aspiration toxicity

Not classified due to lack of data.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

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

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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Product:

##### **Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

##### Components:

##### **Ethylenediaminetetraacetic acid disodium salt dihydrate:**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 41 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 140 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: DIN 38412

Toxicity to microorganisms : EC20 (activated sludge): > 500 mg/l  
Exposure time: 0,5 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

##### **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

#### 12.2 Persistence and degradability

##### Components:

##### **Ethylenediaminetetraacetic acid disodium salt dihydrate:**

Biodegradability : Result: Not readily biodegradable.

#### 12.3 Bioaccumulative potential

##### Components:

##### **Ethylenediaminetetraacetic acid disodium salt dihydrate:**

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

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### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 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.

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

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**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA (Cargo)** : Not regulated as a dangerous good  
**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

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

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

## SECTION 15: Regulatory information

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

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

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- Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable
- Water hazard class (Germany) : WGK 2 obviously hazardous to water  
Classification according to AwSV, Annex 1 (5.2)
- TA Luft List (Germany) : 5.2.1: Total dust:  
others: 24 % urea  
5.2.2: Inorganic substances in powdered form:  
Not applicable  
5.2.4: Inorganic substances in gaseous form:  
Not applicable  
5.2.5: Organic Substances:  
Not applicable  
5.2.7.1.1: Carcinogenic substance:  
Not applicable  
5.2.7.1.1: Quartz fine dust PM4:  
Not applicable  
5.2.7.1.1: Formaldehyde:  
Not applicable  
5.2.7.1.1: fibres:  
Not applicable  
5.2.7.1.2: Germ cell mutagens:  
Not applicable  
5.2.7.1.3: Substances toxic to reproduction:  
Not applicable  
5.2.7.2: Poorly degradable, easily enrichable and highly toxic organic substances:  
Not applicable
- Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)  
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

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|       |   |
|-------|---|
| PICCS | : On the inventory, or in compliance with the inventory |
| IECSC | : On the inventory, or in compliance with the inventory |
| TCSI  | : On the inventory, or in compliance with the inventory |
| TSCA  | : All substances listed as active on the TSCA inventory |
| TECI  | : On the inventory, or in compliance with the inventory |

### 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

|      |   |
|------|---|
| H332 | : Harmful if inhaled.   |
| H373 | : May cause damage to organs through prolonged or repeated exposure if inhaled. |

### Full text of other abbreviations

|            |  |
|------------|--|
| Acute Tox. | : Acute toxicity                                     |
| STOT RE    | : Specific target organ toxicity - repeated 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; AIIC - 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

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High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Distributor

Merck KGaA  
64271 Darmstadt  
Deutschland  
Telephone: +49 (0) 6151 72-0

### 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.

DE / EN / 2304



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

#### 1.1 Product identifier

Trade name : Proteinase K, PCR grade

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

Use of the Substance/Mixture : Laboratory chemicals, Refer to product literature for further details.

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
Sandhoferstrasse 116  
68305 Mannheim  
Germany

Telephone : +496217590  
Telefax : +496217592890  
Responsible Department :  
E-mail address : info.dia-sds@roche.com

#### 1.4 Emergency telephone number

In case of emergencies: : CHEMTREC 0800-181-7059/  
+(49)-69643508409

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

|  |  |
|--|--|
| Skin irritation, Category 2  | H315: Causes skin irritation.  |
| Eye irritation, Category 2   | H319: Causes serious eye irritation.   |
| Respiratory sensitisation, Category 1  | H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Skin sensitisation, Category 1   | H317: May cause an allergic skin reaction.                                       |
| Specific target organ toxicity - single exposure, Category 3, Respiratory system | H335: May cause respiratory irritation.  |

#### 2.2 Label elements

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

Hazard pictograms :



Signal word : Danger

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

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

Precautionary statements :

### Prevention:

P261 Avoid breathing dust.  
P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves/ eye protection/ face protection.  
P284 Wear respiratory protection.

### Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

### Hazardous components which must be listed on the label:

39450-01-6 Proteinase, Triticachium album serine

## 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

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

For explanation of abbreviations see section 16.

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### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- |                         |   |   |
|-------------------------|---|---|
| General advice          | : | Move out of dangerous area.<br>Show this safety data sheet to the doctor in attendance.<br>Do not leave the victim unattended.  |
| If inhaled              | : | Call a physician or poison control centre immediately.<br>Move to fresh air.<br>If unconscious, place in recovery position and seek medical advice.   |
| In case of skin contact | : | If skin irritation persists, call a physician.<br>If on skin, rinse well with water.<br>If on clothes, remove clothes.  |
| In case of eye contact  | : | Immediately flush eye(s) with plenty of water.<br>Remove contact lenses.<br>Protect unharmed eye.<br>Keep eye wide open while rinsing.<br>If eye irritation persists, consult a specialist.   |
| If swallowed            | : | Clean mouth with water and drink afterwards plenty of water.<br>Keep respiratory tract clear.<br>Do not give milk or alcoholic beverages.<br>Never give anything by mouth to an unconscious person.<br>If symptoms persist, call a physician.<br>Take victim immediately to hospital. |

#### 4.2 Most important symptoms and effects, both acute and delayed

- |       |   |  |
|-------|---|--|
| Risks | : | Causes skin irritation.<br>May cause an allergic skin reaction.<br>Causes serious eye irritation.<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>May cause respiratory irritation. |
|-------|---|--|

#### 4.3 Indication of any immediate medical attention and special treatment needed

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

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

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

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Unsuitable extinguishing media : High volume water jet

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : No information available.

Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

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

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.  
Ensure adequate ventilation.

### 6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
Local authorities should be advised if significant spillages cannot be contained.

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

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

### 6.4 Reference to other sections

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

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

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

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Dispose of rinse water in accordance with local and national regulations.

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

Advice on protection against fire and explosion : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures : When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.

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

Storage class (TRGS 510) : 11

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

#### Occupational Exposure Limits

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

### 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

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

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
Effective dust mask

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state : solid  
Colour : white  
Odour : very faint  
Odour Threshold : Not applicable  
Melting point/range : No data available  
Boiling point/boiling range : No data available  
Flammability : Sustains combustion  
Upper explosion limit / Upper flammability limit : No data available

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|  |   |   |
|--|---|---|
| Lower explosion limit / Lower flammability limit | : | No data available                                   |
| Flash point                                      | : | does not flash                                      |
| Auto-ignition temperature                        | : | No data available                                   |
| Decomposition temperature                        | : | No data available                                   |
| pH   | : | 6,5<br>Concentration: 20 %<br>(as aqueous solution) |
| Viscosity  |   |   |
| Viscosity, dynamic                               | : | Not applicable                                      |
| Viscosity, kinematic                             | : | Not applicable                                      |
| Solubility(ies)                                  |   |   |
| Water solubility                                 | : | completely soluble                                  |
| Solubility in other solvents                     | : | No data available                                   |
| Partition coefficient: n-octanol/water           | : | No data available                                   |
| Vapour pressure                                  | : | No data available                                   |
| Relative density                                 | : | No data available                                   |
| Relative vapour density                          | : | Not applicable                                      |
| Particle characteristics                         |   |   |
| Particle Size Distribution                       | : | No data available                                   |

### 9.2 Other information

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

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

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### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.  
No decomposition if stored and applied as directed.

### 10.4 Conditions to avoid

Conditions to avoid : Heat

### 10.5 Incompatible materials

Materials to avoid : No data available

### 10.6 Hazardous decomposition products

No data available

## SECTION 11: Toxicological information

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

#### Acute toxicity

Not classified due to lack of data.

#### Skin corrosion/irritation

Causes skin irritation.

#### Product:

Remarks : May cause skin irritation and/or dermatitis.

#### Components:

##### Proteinase, Tritirachium album serine:

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

#### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Product:

Remarks : May cause irreversible eye damage.

#### Components:

##### Proteinase, Tritirachium album serine:

Result : Irritating to eyes.  
Remarks : May cause irreversible eye damage.



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### 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.

#### Product:

Remarks : Causes sensitisation.

#### Components:

##### Proteinase, Tritirachium album serine:

Assessment : May cause sensitisation by skin contact.

Remarks : Causes sensitisation.

Assessment : May cause sensitisation by inhalation.

### Germ cell mutagenicity

Not classified due to lack of data.

### Carcinogenicity

Not classified due to lack of data.

### Reproductive toxicity

Not classified due to lack of data.

### STOT - single exposure

May cause respiratory irritation.

#### Components:

##### Proteinase, Tritirachium album serine:

Assessment : May cause respiratory irritation.

### STOT - repeated exposure

Not classified due to lack of data.

#### Components:

##### Proteinase, Tritirachium album serine:

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

### Aspiration toxicity

Not classified due to lack of data.

#### Components:

##### Proteinase, Tritirachium album serine:

No data available

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### 11.2 Information on other hazards

#### Endocrine disrupting properties

##### Product:

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

## SECTION 12: Ecological information

### 12.1 Toxicity

##### Product:

#### Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

##### Components:

#### Proteinase, Tritirachium album serine:

#### Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

##### Components:

#### Proteinase, Tritirachium album serine:

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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

##### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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### 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.

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

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### 14.4 Packing group

ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA (Cargo) : Not regulated as a dangerous good  
IATA (Passenger) : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

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

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

## SECTION 15: Regulatory information

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

**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 **75**  
If you intend to use this product as tattoo ink, please contact your vendor.

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council : Not applicable

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on the control of major-  
accident hazards involving  
dangerous substances.

Water hazard class : WGK 1 slightly hazardous to water  
(Germany) Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : 5.2.1: Total dust:  
5.2.2: Inorganic substances in powdered form:  
Not applicable  
5.2.4: Inorganic substances in gaseous form:  
Not applicable  
5.2.5: Organic Substances:  
Not applicable  
5.2.7.1.1: Carcinogenic substance:  
Not applicable  
5.2.7.1.1: Quartz fine dust PM4:  
Not applicable  
5.2.7.1.1: Formaldehyde:  
Not applicable  
5.2.7.1.1: fibres:  
Not applicable  
5.2.7.1.2: Germ cell mutagens:  
Not applicable  
5.2.7.1.3: Substances toxic to reproduction:  
Not applicable  
5.2.7.2: Poorly degradable, easily enrichable and highly toxic  
organic substances:  
Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial  
emissions (integrated pollution prevention and control)  
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.

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

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not  
on the Canadian DSL nor NDSL.  
  
Proteinase, Tritirachium album serine

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

ENCS : Not in compliance with the inventory

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|       |   |
|-------|---|
| 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                        |

### 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

|      |  |
|------|--|
| H315 | : Causes skin irritation.  |
| H317 | : May cause an allergic skin reaction.                                       |
| H319 | : Causes serious eye irritation.   |
| H334 | : May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H335 | : May cause respiratory irritation.  |

### Full text of other abbreviations

|             |  |
|-------------|--|
| Eye Irrit.  | : Eye irritation                                   |
| Resp. Sens. | : Respiratory sensitisation                        |
| Skin Irrit. | : Skin irritation                                  |
| Skin Sens.  | : Skin sensitisation                               |
| STOT SE     | : Specific target organ toxicity - single exposure |

### Classification of the mixture:

|               |      |
|---------------|------|
| Skin Irrit. 2 | H315 |
| Eye Irrit. 2  | H319 |
| Resp. Sens. 1 | H334 |
| Skin Sens. 1  | H317 |
| STOT SE 3     | H335 |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

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 -

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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; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Distributor

Merck KGaA  
64271 Darmstadt  
Deutschland  
Telephone: +49 (0) 6151 72-0

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

#### 1.1 Product identifier

Trade name : Wash Buffer I / Inhibitor Removal Buffer

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

Use of the Substance/Mixture : Laboratory chemicals, Refer to product literature for further details.

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
Sandhoferstrasse 116  
68305 Mannheim  
Germany

Telephone : +496217590  
Telefax : +496217592890  
Responsible Department :  
E-mail address : info.dia-sds@roche.com

#### 1.4 Emergency telephone number

In case of emergencies: : CHEMTREC 0800-181-7059/  
+(49)-69643508409

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

|                             |                                      |
|-----------------------------|--------------------------------------|
| Acute toxicity, Category 4  | H302: Harmful if swallowed.          |
| Acute toxicity, Category 4  | H332: Harmful if inhaled.            |
| Skin irritation, Category 2 | H315: Causes skin irritation.        |
| Eye irritation, Category 2  | H319: Causes serious eye irritation. |

#### 2.2 Label elements

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

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 + H332 Harmful if swallowed or if inhaled.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**  
P261 Avoid breathing mist or vapours.



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P264 Wash skin thoroughly after handling.  
P280 Wear protective gloves/ eye protection/ face protection.

### Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.

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

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Hazardous components which must be listed on the label:

50-01-1 guanidinium chloride

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name        | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number    | Classification   | Concentration<br>(% w/w) |
|----------------------|--|--|--------------------------|
| guanidinium chloride | 50-01-1<br>200-002-3<br>607-148-00-0<br>01-2119977063-35 | Acute Tox. 4; H302<br>Acute Tox. 4; H332<br>Skin Irrit. 2; H315<br>Eye Irrit. 2; H319<br>Acute toxicity estimate<br><br>Acute oral toxicity:<br>475 mg/kg<br>Acute inhalation<br>toxicity (dust/mist):<br>3,2 mg/l | >= 50,0 - <<br>70,0      |

For explanation of abbreviations see section 16.

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### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- |                         |   |   |
|-------------------------|---|---|
| General advice          | : | Move out of dangerous area.<br>Show this safety data sheet to the doctor in attendance.<br>Do not leave the victim unattended.  |
| If inhaled              | : | Move to fresh air.<br>If unconscious, place in recovery position and seek medical advice.<br>If symptoms persist, call a physician.   |
| In case of skin contact | : | If skin irritation persists, call a physician.<br>If on skin, rinse well with water.<br>If on clothes, remove clothes.  |
| In case of eye contact  | : | Immediately flush eye(s) with plenty of water.<br>Remove contact lenses.<br>Protect unharmed eye.<br>Keep eye wide open while rinsing.<br>If eye irritation persists, consult a specialist.   |
| If swallowed            | : | Clean mouth with water and drink afterwards plenty of water.<br>Keep respiratory tract clear.<br>Do not give milk or alcoholic beverages.<br>Never give anything by mouth to an unconscious person.<br>If symptoms persist, call a physician. |

#### 4.2 Most important symptoms and effects, both acute and delayed

- |       |   |  |
|-------|---|--|
| Risks | : | Harmful if swallowed or if inhaled.<br>Causes skin irritation.<br>Causes serious eye irritation. |
|-------|---|--|

#### 4.3 Indication of any immediate medical attention and special treatment needed

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

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- |                                |   |   |
|--------------------------------|---|---|
| Suitable extinguishing media   | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Unsuitable extinguishing media | : | High volume water jet   |

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### 5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : No information available.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Ammonia  
Gaseous hydrogen chloride (HCl).

### 5.3 Advice for firefighters

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

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.  
Refer to protective measures listed in sections 7 and 8.

### 6.2 Environmental precautions

Environmental precautions : Prevent further leakage or spillage if safe to do so.  
Local authorities should be advised if significant spillages cannot be contained.

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

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).  
Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

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

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advice on safe handling : Do not breathe vapours/dust.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

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Hygiene measures : When using do not eat or drink. When using do not smoke.  
Wash hands before breaks and at the end of workday.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.

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

Storage class (TRGS 510) : 12

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

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Engineering measures

No data available

#### Personal protective equipment

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

Hand protection

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

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concentration of the dangerous substance at the work place.

### SECTION 9: Physical and chemical properties

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

|  |   |
|--|---|
| Physical state                                   | : liquid  |
| Colour   | : colourless  |
| Odour  | : odourless   |
| Odour Threshold                                  | : No data available   |
| Melting point/range                              | : -23 °C  |
| Boiling point/boiling range                      | : 107 °C  |
| 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   |
| Flash point                                      | : does not flash  |
| Auto-ignition temperature                        | : No data available   |
| Decomposition temperature                        | : No data available   |
| pH   | : 5,8 - 7,8   |
| 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   |
| Density  | : 1,187 g/cm <sup>3</sup> (20 °C)                             |

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Relative vapour density : No data available

Particle characteristics  
Particle Size Distribution : Not applicable

### 9.2 Other information

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

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Reacts with the following substances:  
Oxidizing agents  
No decomposition if stored and applied as directed.

### 10.4 Conditions to avoid

Conditions to avoid : No data available

### 10.5 Incompatible materials

Materials to avoid : No data available

### 10.6 Hazardous decomposition products

In case of fire hazardous decomposition products may be produced such as:

Carbon oxides

Nitrogen oxides (NO<sub>x</sub>)

Gaseous hydrogen chloride (HCl).

Ammonia

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### SECTION 11: Toxicological information

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

##### Acute toxicity

Harmful if swallowed or if inhaled.

##### Product:

Acute oral toxicity : Acute toxicity estimate: 735,29 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 4,95 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

##### Components:

##### **guanidinium chloride:**

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

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

##### **Skin corrosion/irritation**

Causes skin irritation.

##### Product:

Remarks : May cause skin irritation in susceptible persons.

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### **Components:**

#### **guanidinium chloride:**

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

### **Serious eye damage/eye irritation**

Causes serious eye irritation.

### **Product:**

Remarks : May cause irreversible eye damage.

### **Components:**

#### **guanidinium chloride:**

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

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified due to lack of data.

#### **Respiratory sensitisation**

Not classified due to lack of data.

### **Components:**

#### **guanidinium chloride:**

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

### **Germ cell mutagenicity**

Not classified due to lack of data.

### **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



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Method: OECD Test Guideline 473  
Result: negative  
GLP: no

### **Carcinogenicity**

Not classified due to lack of data.

### **Reproductive toxicity**

Not classified due to lack of data.

### **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

### **STOT - single exposure**

Not classified due to lack of data.

### **STOT - repeated exposure**

Not classified due to lack of data.

### **Repeated dose toxicity**

### **Components:**

#### **guanidinium chloride:**

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

### **Aspiration toxicity**

Not classified due to lack of data.

## **11.2 Information on other hazards**

### **Endocrine disrupting properties**

### **Product:**

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

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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Product:

##### **Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

##### Components:

##### **guanidinium chloride:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 1.758 mg/l  
End point: mortality  
Exposure time: 48 h  
Test Type: static test  
GLP: yes

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

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

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

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End point: Growth rate  
Exposure time: 18 h  
Test Type: static test  
Method: DIN 38 412 Part 8  
GLP: yes

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 2,9 mg/l  
End point: reproduction rate  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Analytical monitoring: yes  
Method: OECD Test Guideline 211  
GLP: No information available.

### Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

## 12.2 Persistence and degradability

### 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).

## 12.3 Bioaccumulative potential

### Components:

#### **guanidinium chloride:**

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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 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.

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good

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IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.4 Packing group

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

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

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

## SECTION 15: Regulatory information

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

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 **75**, 3

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : If you intend to use this product as tattoo ink, please contact your vendor.

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

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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

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

Water hazard class (Germany) : WGK 1 slightly hazardous to water  
Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : 5.2.1: Total dust:  
5.2.2: Inorganic substances in powdered form:  
Not applicable  
5.2.4: Inorganic substances in gaseous form:  
Not applicable  
5.2.5: Organic Substances:  
Not applicable  
5.2.7.1.1: Carcinogenic substance:  
Not applicable  
5.2.7.1.1: Quartz fine dust PM4:  
Not applicable  
5.2.7.1.1: Formaldehyde:  
Not applicable  
5.2.7.1.1: fibres:  
Not applicable  
5.2.7.1.2: Germ cell mutagens:  
Not applicable  
5.2.7.1.3: Substances toxic to reproduction:  
Not applicable  
5.2.7.2: Poorly degradable, easily enrichable and highly toxic organic substances:  
Not applicable

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

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### 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  |

### 15.2 Chemical safety assessment

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

## SECTION 16: Other information

### Full text of H-Statements

|      |                                  |
|------|----------------------------------|
| H302 | : Harmful if swallowed.          |
| H315 | : Causes skin irritation.        |
| H319 | : Causes serious eye irritation. |
| H332 | : Harmful if inhaled.            |

### Full text of other abbreviations

|             |                   |
|-------------|-------------------|
| Acute Tox.  | : Acute toxicity  |
| Eye Irrit.  | : Eye irritation  |
| Skin Irrit. | : Skin irritation |

### Classification of the mixture:

|               |      |
|---------------|------|
| Acute Tox. 4  | H302 |
| Acute Tox. 4  | H332 |
| Skin Irrit. 2 | H315 |
| Eye Irrit. 2  | H319 |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

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

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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; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Distributor

Merck KGaA  
64271 Darmstadt  
Deutschland  
Telephone: +49 (0) 6151 72-0

### 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.

DE / EN / 2304



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## High Pure PCR Template Preparation Kit

Version  
1.3

Revision Date:  
03.04.2024

Date of last issue: 03.04.2024  
Date of first issue: 27.01.2023

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

#### 1.1 Product identifier

Trade name : Wash buffer

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

Use of the Substance/Mixture : Laboratory chemicals, Refer to product literature for further details.

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
Sandhoferstrasse 116  
68305 Mannheim  
Germany

Telephone : +496217590  
Telefax : +496217592890  
Responsible Department :  
E-mail address : info.dia-sds@roche.com

#### 1.4 Emergency telephone number

In case of emergencies: : CHEMTREC 0800-181-7059/  
+(49)-69643508409

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

Not a hazardous substance or mixture.

#### 2.2 Label elements

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

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

#### 3.2 Mixtures

##### Components

For explanation of abbreviations see section 16.

Remarks : No hazardous ingredients

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

None known.

#### 4.3 Indication of any immediate medical attention and special treatment needed

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

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

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

#### 5.2 Special hazards arising from the substance or mixture

- Specific hazards during : No information available.

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firefighting

Hazardous combustion products : No hazardous combustion products are known

### 5.3 Advice for firefighters

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

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

## SECTION 6: Accidental release measures

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

Personal precautions : Refer to protective measures listed in sections 7 and 8.

### 6.2 Environmental precautions

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

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

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

### 6.4 Reference to other sections

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

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : 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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Advice on common storage : No materials to be especially mentioned.

Storage class (TRGS 510) : 12

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

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Engineering measures

No data available

#### Personal protective equipment

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

Safety glasses

#### 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 : Protective suit

Respiratory protection : No personal respiratory protective equipment normally

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required.

### SECTION 9: Physical and chemical properties

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

|  |                       |
|--|-----------------------|
| 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   |
| Upper explosion limit / Upper flammability limit | : No data available   |
| Lower explosion limit / Lower flammability limit | : No data available   |
| Flash point                                      | : No data available   |
| Auto-ignition temperature                        | : No data available   |
| Decomposition temperature                        | : No data available   |
| pH   | : 7,4 - 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   |
| Relative vapour density                          | : No data available   |
| Particle characteristics                         |                       |
| Particle Size Distribution                       | : Not applicable      |

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### 9.2 Other information

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

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

|                     |   |  |
|---------------------|---|--|
| Hazardous reactions | : | No dangerous reaction known under conditions of normal use.<br><br>Stable under recommended storage conditions.<br>No hazards to be specially mentioned. |
|---------------------|---|--|

### 10.4 Conditions to avoid

|                     |   |                   |
|---------------------|---|-------------------|
| Conditions to avoid | : | No data available |
|---------------------|---|-------------------|

### 10.5 Incompatible materials

|                    |   |                   |
|--------------------|---|-------------------|
| Materials to avoid | : | No data available |
|--------------------|---|-------------------|

### 10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

## SECTION 11: Toxicological information

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

#### Acute toxicity

Not classified due to lack of data.

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### **Skin corrosion/irritation**

Not classified due to lack of data.

### **Serious eye damage/eye irritation**

Not classified due to lack of data.

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified due to lack of data.

#### **Respiratory sensitisation**

Not classified due to lack of data.

### **Germ cell mutagenicity**

Not classified due to lack of data.

### **Carcinogenicity**

Not classified due to lack of data.

### **Reproductive toxicity**

Not classified due to lack of data.

### **STOT - single exposure**

Not classified due to lack of data.

### **STOT - repeated exposure**

Not classified due to lack of data.

### **Aspiration toxicity**

Not classified due to lack of data.

## **11.2 Information on other hazards**

### **Endocrine disrupting properties**

#### **Product:**

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

## **SECTION 12: Ecological information**

### **12.1 Toxicity**

#### **Product:**

#### **Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

### **12.2 Persistence and degradability**

No data available

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### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 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.

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good



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IATA : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.4 Packing group

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

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

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

## SECTION 15: Regulatory information

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

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

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- Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable
- Water hazard class (Germany) : nwg not water endangering  
Classification according to AwSV, Annex 1 (2.2)
- TA Luft List (Germany) : 5.2.1: Total dust:  
5.2.2: Inorganic substances in powdered form:  
Not applicable  
5.2.4: Inorganic substances in gaseous form:  
Not applicable  
5.2.5: Organic Substances:  
Not applicable  
5.2.7.1.1: Carcinogenic substance:  
Not applicable  
5.2.7.1.1: Quartz fine dust PM4:  
Not applicable  
5.2.7.1.1: Formaldehyde:  
Not applicable  
5.2.7.1.1: fibres:  
Not applicable  
5.2.7.1.2: Germ cell mutagens:  
Not applicable  
5.2.7.1.3: Substances toxic to reproduction:  
Not applicable  
5.2.7.2: Poorly degradable, easily enrichable and highly toxic organic substances:  
Not applicable
- Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)  
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

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|       |   |   |
|-------|---|---|
| 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                  |

### 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 other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

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### Distributor

Merck KGaA  
64271 Darmstadt  
Deutschland  
Telephone: +49 (0) 6151 72-0

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

#### 1.1 Product identifier

Trade name : Elution Buffer

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

Use of the Substance/Mixture : Laboratory chemicals, Refer to product literature for further details.

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
Sandhoferstrasse 116  
68305 Mannheim  
Germany

Telephone : +496217590  
Telefax : +496217592890  
Responsible Department :  
E-mail address : info.dia-sds@roche.com

#### 1.4 Emergency telephone number

In case of emergencies: : CHEMTREC 0800-181-7059/  
+(49)-69643508409

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

Not a hazardous substance or mixture.

#### 2.2 Label elements

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

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

#### 3.2 Mixtures

##### Components

For explanation of abbreviations see section 16.

Remarks : No hazardous ingredients

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

General advice : Do not leave the victim unattended.

If inhaled : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

None known.

#### 4.3 Indication of any immediate medical attention and special treatment needed

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

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

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

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during : No information available.

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firefighting

Hazardous combustion products : No hazardous combustion products are known

### 5.3 Advice for firefighters

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

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

## SECTION 6: Accidental release measures

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

Personal precautions : Refer to protective measures listed in sections 7 and 8.

### 6.2 Environmental precautions

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

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

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

### 6.4 Reference to other sections

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

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : 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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Advice on common storage : No materials to be especially mentioned.

Storage class (TRGS 510) : 12

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

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Engineering measures

No data available

#### Personal protective equipment

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

#### 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 : Protective suit

Respiratory protection : No personal respiratory protective equipment normally



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required.

### SECTION 9: Physical and chemical properties

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

|  |                           |
|--|---------------------------|
| Physical state                                   | : liquid                  |
| Colour   | : colourless              |
| Odour  | : odourless               |
| Odour Threshold                                  | : No data available       |
| Melting point/range                              | : 3 °C                    |
| Boiling point/boiling range                      | : 101 °C                  |
| Flammability                                     | : No data available       |
| Upper explosion limit / Upper flammability limit | : No data available       |
| Lower explosion limit / Lower flammability limit | : No data available       |
| Flash point                                      | : does not flash          |
| Auto-ignition temperature                        | : No data available       |
| Decomposition temperature                        | : No data available       |
| pH   | : 7,5 - 9,5               |
| Viscosity  |                           |
| Viscosity, dynamic                               | : No data available       |
| Viscosity, kinematic                             | : No data available       |
| Solubility(ies)                                  |                           |
| Water solubility                                 | : completely miscible     |
| Solubility in other solvents                     | : No data available       |
| Partition coefficient: n-octanol/water           | : No data available       |
| Vapour pressure                                  | : No data available       |
| Relative density                                 | : No data available       |
| Density  | : 0,998 g/cm <sup>3</sup> |

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Relative vapour density : No data available

Particle characteristics

Particle Size Distribution : Not applicable

### 9.2 Other information

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 : completely miscible

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

Stable under recommended storage conditions.  
No hazards to be specially mentioned.

### 10.4 Conditions to avoid

Conditions to avoid : No data available

### 10.5 Incompatible materials

Materials to avoid : No data available

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

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

#### Acute toxicity

Not classified due to lack of data.

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### **Skin corrosion/irritation**

Not classified due to lack of data.

### **Serious eye damage/eye irritation**

Not classified due to lack of data.

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified due to lack of data.

#### **Respiratory sensitisation**

Not classified due to lack of data.

### **Germ cell mutagenicity**

Not classified due to lack of data.

### **Carcinogenicity**

Not classified due to lack of data.

### **Reproductive toxicity**

Not classified due to lack of data.

### **STOT - single exposure**

Not classified due to lack of data.

### **STOT - repeated exposure**

Not classified due to lack of data.

### **Aspiration toxicity**

Not classified due to lack of data.

## **11.2 Information on other hazards**

### **Endocrine disrupting properties**

#### **Product:**

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

## **SECTION 12: Ecological information**

### **12.1 Toxicity**

#### **Product:**

#### **Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

### **12.2 Persistence and degradability**

No data available

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### 12.3 Bioaccumulative potential

No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 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.

### 12.7 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

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**IATA** : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### 14.4 Packing group

**ADR** : Not regulated as a dangerous good

**RID** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA (Cargo)** : Not regulated as a dangerous good

**IATA (Passenger)** : Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

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

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

## SECTION 15: Regulatory information

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

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

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

: Not applicable

Water hazard class  
(Germany)

: nwg not water endangering

TA Luft List (Germany)

: 5.2.1: Total dust:  
5.2.2: Inorganic substances in powdered form:  
Not applicable  
5.2.4: Inorganic substances in gaseous form:  
Not applicable  
5.2.5: Organic Substances:  
Not applicable  
5.2.7.1.1: Carcinogenic substance:  
Not applicable  
5.2.7.1.1: Quartz fine dust PM4:  
Not applicable  
5.2.7.1.1: Formaldehyde:  
Not applicable  
5.2.7.1.1: fibres:  
Not applicable  
5.2.7.1.2: Germ cell mutagens:  
Not applicable  
5.2.7.1.3: Substances toxic to reproduction:  
Not applicable  
5.2.7.2: Poorly degradable, easily enrichable and highly toxic  
organic substances:  
Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial  
emissions (integrated pollution prevention and control)  
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

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|       |   |
|-------|---|
| PICCS | : On the inventory, or in compliance with the inventory |
| IECSC | : On the inventory, or in compliance with the inventory |
| TCSI  | : On the inventory, or in compliance with the inventory |
| TSCA  | : All substances listed as active on the TSCA inventory |
| TECI  | : On the inventory, or in compliance with the inventory |

### 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 other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Distributor

Merck KGaA

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

#### 1.1 Product identifier

Trade name : Binding buffer, universal MBF

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

Use of the Substance/Mixture : Laboratory chemicals, Refer to product literature for further details.

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
Sandhoferstrasse 116  
68305 Mannheim  
Germany

Telephone : +496217590  
Telefax : +496217592890  
Responsible Department :  
E-mail address : info.dia-sds@roche.com

#### 1.4 Emergency telephone number

In case of emergencies: : CHEMTREC 0800-181-7059/  
+(49)-69643508409

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

Acute toxicity, Category 4 H302: Harmful if swallowed.  
Skin irritation, Category 2 H315: Causes skin irritation.  
Serious eye damage, Category 1 H318: Causes serious eye damage.

#### 2.2 Label elements

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

Hazard pictograms :



Signal word : Danger

Hazard statements : H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H318 Causes serious eye damage.

Precautionary statements : **Prevention:**  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P280 Wear protective gloves/ eye protection/ face protection.

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### Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Hazardous components which must be listed on the label:

|           |   |
|-----------|---|
| 50-01-1   | guanidinium chloride  |
| 9002-92-0 | Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy- |

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name        | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number    | Classification   | Concentration<br>(% w/w) |
|----------------------|--|--|--------------------------|
| guanidinium chloride | 50-01-1<br>200-002-3<br>607-148-00-0<br>01-2119977063-35 | Acute Tox. 4; H302<br>Acute Tox. 4; H332<br>Skin Irrit. 2; H315<br>Eye Irrit. 2; H319<br>Acute toxicity estimate<br><br>Acute oral toxicity:<br>475 mg/kg<br>Acute inhalation<br>toxicity (dust/mist):<br>3,2 mg/l | $\geq 30,0$ - $< 50,0$   |

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|   |                        |  |                        |
|---|------------------------|--|------------------------|
| Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy- | 9002-92-0<br>500-002-6 | Acute Tox. 4; H302<br>Eye Dam. 1; H318<br><u>Aquatic Chronic 3;</u><br>H412<br>Acute toxicity<br>estimate<br><br>Acute oral toxicity:<br>1.000 mg/kg | $\geq 10,0$ - $< 20,0$ |
|---|------------------------|--|------------------------|

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 : Move to fresh air.  
If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If skin irritation persists, call a physician.  
If on skin, rinse well with water.  
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.  
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
Continue rinsing eyes during transport to hospital.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.  
Keep respiratory tract clear.  
Do NOT induce vomiting.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Take victim immediately to hospital.

#### 4.2 Most important symptoms and effects, both acute and delayed

- Risks : Harmful if swallowed.  
Causes skin irritation.

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Causes serious eye damage.

### 4.3 Indication of any immediate medical attention and special treatment needed

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

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

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

Unsuitable extinguishing media : High volume water jet

### 5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Ammonia  
Gaseous hydrogen chloride (HCl).  
Carbon monoxide  
Carbon dioxide (CO<sub>2</sub>)

### 5.3 Advice for firefighters

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

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.  
Refer to protective measures listed in sections 7 and 8.

### 6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.

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

Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).  
Keep in suitable, closed containers for disposal.

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### 6.4 Reference to other sections

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

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- Advice on safe handling : Do not breathe vapours/dust.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.  
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.
- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Hygiene measures : When using do not eat or drink. When using do not smoke.  
Wash hands before breaks and at the end of workday.

### 7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully 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
- Advice on common storage : Keep away from oxidizing agents, strongly alkaline and strongly acid materials in order to avoid exothermic reactions.
- Storage class (TRGS 510) : 12
- 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

Contains no substances with occupational exposure limit values.

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### 8.2 Exposure controls

#### Engineering measures

No data available

#### Personal protective equipment

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

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

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.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

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

Flash point : does not flash

Auto-ignition temperature : No data available

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|  |   |  |
|--|---|--|
| Decomposition temperature              | : | No data available                                |
| pH                                     | : | 3 - 5 (25 °C)                                    |
| Viscosity                              |   |  |
| Viscosity, dynamic                     | : | No data available                                |
| Viscosity, kinematic                   | : | No data available                                |
| Solubility(ies)                        |   |  |
| Water solubility                       | : | completely miscible                              |
| Solubility in other solvents           | : | No data available                                |
| Partition coefficient: n-octanol/water | : | No data available                                |
| Vapour pressure                        | : | No data available                                |
| Relative density                       | : | No data available                                |
| Density                                | : | 1,148 g/cm <sup>3</sup> (20 °C, 990 - 1.030 hPa) |
| Relative vapour density                | : | No data available                                |
| Particle characteristics               |   |  |
| Particle Size Distribution             | : | Not applicable                                   |

### 9.2 Other information

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

---

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Reacts with the following substances:

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Oxidizing agents  
Keep away from heat and sources of ignition.  
No decomposition if stored and applied as directed.

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

### 10.5 Incompatible materials

Materials to avoid : Strong acids and oxidizing agents  
Bases

### 10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

## SECTION 11: Toxicological information

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

#### Acute toxicity

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 1.181 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

#### Components:

##### guanidinium chloride:

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

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



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

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.

### **Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:**

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

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

### **Skin corrosion/irritation**

Causes skin irritation.

#### **Product:**

Remarks : May cause skin irritation in susceptible persons.

#### **Components:**

##### **guanidinium chloride:**

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

### **Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:**

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.

#### **Product:**

Remarks : May cause irreversible eye damage.

#### **Components:**

##### **guanidinium chloride:**

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

### **Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:**

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

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified due to lack of data.

#### **Respiratory sensitisation**

Not classified due to lack of data.

### **Components:**

#### **guanidinium chloride:**

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

### **Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:**

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

### **Germ cell mutagenicity**

Not classified due to lack of data.

### **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

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### **Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:**

- 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 due to lack of data.

### **Reproductive toxicity**

Not classified due to lack of data.

### **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

### **Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:**

- 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 due to lack of data.

### **STOT - repeated exposure**

Not classified due to lack of data.

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### 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                       |

##### **Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:**

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

### Aspiration toxicity

Not classified due to lack of data.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

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

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Product:

##### **Ecotoxicology Assessment**

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

|   |                     |
|---|---------------------|
| Other organisms relevant to the environment | : No data available |
|---|---------------------|

#### Components:

##### **guanidinium chloride:**

|                  |  |
|------------------|--|
| Toxicity to fish | : LC50 (Leuciscus idus (Golden orfe)): 1.758 mg/l<br>End point: mortality<br>Exposure time: 48 h<br>Test Type: static test<br>GLP: yes |
|------------------|--|

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|  |   |
|--|---|
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): 70,2 mg/l<br>End point: Immobilization<br>Exposure time: 48 h<br>Test Type: static test<br>Analytical monitoring: yes<br>Method: OECD Test Guideline 202<br>GLP: No information available.   |
| Toxicity to algae/aquatic plants                                       | : EC50 (Pseudokirchneriella subcapitata (green algae)): 33,5 mg/l<br>End point: Growth rate<br>Exposure time: 72 h<br>Test Type: static test<br>Analytical monitoring: yes<br>Method: Regulation (EC) No. 440/2008, Annex, C.3<br>GLP: yes<br><br>EC50 (Pseudokirchneriella subcapitata (green algae)): 11,8 mg/l<br>Exposure time: 72 h<br>Test Type: static test<br>Analytical monitoring: yes<br>Method: Regulation (EC) No. 440/2008, Annex, C.3<br>GLP: yes<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 6,3 mg/l<br>End point: Growth rate<br>Exposure time: 72 h<br>Test Type: static test<br>Analytical monitoring: yes<br>Method: Regulation (EC) No. 440/2008, Annex, C.3<br>GLP: yes |
| Toxicity to microorganisms   | : EC10 (Pseudomonas putida): 7.125 mg/l<br>End point: Growth rate<br>Exposure time: 18 h<br>Test Type: static test<br>Method: DIN 38 412 Part 8<br>GLP: yes   |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC: > 181 mg/l<br>End point: mortality<br>Exposure time: 35 d<br>Species: Pimephales promelas (fathead minnow)<br>Test Type: flow-through test<br>Analytical monitoring: yes<br>Method: OECD Test Guideline 210<br>GLP: No information available.   |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 2,9 mg/l<br>End point: reproduction rate<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Analytical monitoring: yes  |

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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

### Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:

- 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 microorganisms : (Photobacterium phosphoreum): 2,5 mg/l  
Test Type: EC50
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,144 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: QSAR

### Ecotoxicology Assessment

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

## 12.2 Persistence and degradability

### 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).

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### **Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:**

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

### 12.3 Bioaccumulative potential

#### **Components:**

##### **guanidinium chloride:**

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

### **Poly(oxy-1,2-ethanediyl), $\alpha$ -dodecyl- $\omega$ -hydroxy-:**

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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 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.

### 12.7 Other adverse effects

#### **Product:**

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Harmful to aquatic life with long lasting effects.

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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

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

### SECTION 14: Transport information

#### 14.1 UN number or ID number

- ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

#### 14.2 UN proper shipping name

- ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

- ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

#### 14.4 Packing group

- ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA (Cargo) : Not regulated as a dangerous good  
IATA (Passenger) : Not regulated as a dangerous good



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### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

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

### 14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

## SECTION 15: Regulatory information

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

|   |   |
|---|---|
| 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:<br>Number on list <b>75</b> , 3 |
| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)              | If you intend to use this product as tattoo ink, please contact your vendor.                                |
| 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  |
| Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. | : Not applicable  |
| Water hazard class (Germany)  | : WGK 2 obviously hazardous to water<br>Classification according to AwSV, Annex 1 (5.2)                     |
| TA Luft List (Germany)  | : 5.2.1: Total dust:  |

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others: 0,05 % urea  
5.2.2: Inorganic substances in powdered form:  
Not applicable  
5.2.4: Inorganic substances in gaseous form:  
Not applicable  
5.2.5: Organic Substances:  
Not applicable  
5.2.7.1.1: Carcinogenic substance:  
Not applicable  
5.2.7.1.1: Quartz fine dust PM4:  
Not applicable  
5.2.7.1.1: Formaldehyde:  
Not applicable  
5.2.7.1.1: fibres:  
Not applicable  
5.2.7.1.2: Germ cell mutagens:  
Not applicable  
5.2.7.1.3: Substances toxic to reproduction:  
Not applicable  
5.2.7.2: Poorly degradable, easily enrichable and highly toxic organic substances:  
Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)  
Volatile organic compounds (VOC) content: 17,42 %

### 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

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### 15.2 Chemical safety assessment

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

### SECTION 16: Other information

#### Full text of H-Statements

|      |   |  |
|------|---|--|
| H302 | : | Harmful if swallowed.                              |
| H315 | : | Causes skin irritation.                            |
| H318 | : | Causes serious eye damage.                         |
| H319 | : | Causes serious eye irritation.                     |
| H332 | : | Harmful if inhaled.                                |
| 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                     |
| Skin Irrit.     | : | Skin irritation                    |

#### Classification of the mixture:

|               |      |
|---------------|------|
| Acute Tox. 4  | H302 |
| Skin Irrit. 2 | H315 |
| Eye Dam. 1    | H318 |

#### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |

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

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Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Distributor

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### 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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