

KAPA MG Kit

Version
4.1

Revision Date:
03.04.2024

Date of last issue: 03.04.2024
Date of first issue: 19.05.2016

Cover letter for product:

Trade name : KAPA MG Kit
Product code : 07961693001

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

- 1) KAPA NGS Extraction Buffer (10X)
- 2) KAPA NGS Extraction Enzyme (1 U/uL)
- 3) KAPA2G Robust HotStart ReadyMix (2X)

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

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 Harmful if swallowed.
H371 May cause damage to organs.

Precautionary statements : **Prevention:**
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

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

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

Not assigned by regulation

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according to Regulation (EC) No. 1907/2006



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

1.1 Product identifier

Trade name : KAPA NGS Extraction Buffer (10X)

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
Deutschland

Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH

Centre for detoxification: : Mainz +49(0)6131-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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.

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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_x)

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 : See label, package insert or internal guidelines

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storage conditions

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

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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 : No data available

Odour : No data available

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

Decomposition temperature : No data available

pH : 9,0

Viscosity

 Viscosity, dynamic : No data available

 Viscosity, kinematic : No data available

Solubility(ies)

 Water solubility : completely miscible

 Solubility in other solvents : No data available

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

Vapour pressure : No data available

Relative density : No data available

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Density : 1,005 g/cm³
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

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 : 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

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

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

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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)

ADR : Not regulated as a dangerous good

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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**
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

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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:
Class 3: 0,21 % hydrogen chloride
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: 0,1 %

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

- AIIC : On the inventory, or in compliance with the inventory
- DSL : All components of this product are on the Canadian DSL
- NZIoC : On the inventory, or in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : On the inventory, or in compliance with the inventory

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

Further information

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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 : KAPA NGS Extraction Enzyme (1 U/uL)

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
Deutschland

Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH

Centre for detoxification: : Mainz +49(0)6131-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Thermolysin	9073-78-3 232-973-4	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Resp. Sens. 1; H334 STOT SE 3; H335 (Respiratory system)	< 0,1
Substances with a workplace exposure limit :			
glycerol	56-81-5 200-289-5 01-2119471987-18	Not classified	>= 50,0 - < 70,0

For explanation of abbreviations see section 16.

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.

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4.3 Indication of any immediate medical attention and special treatment needed

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

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : 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 : 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 : 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.

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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

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
glycerol	56-81-5	AGW (Inhalable fraction)	200 mg/m ³	DE TRGS 900
	Peak-limit: excursion factor (category): 2;(I)			
	Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			
Thermolysin	9073-78-3	IOEL	0,00006 mg/m ³	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.

Safety glasses

Hand protection

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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 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 : 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

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Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	7,9
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 ³
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

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

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Hazardous reactions : 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

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.

Components:

glycerol:

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

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m³
Exposure time: 7 h
Test atmosphere: vapour
GLP: no
Assessment: The component/mixture is minimally toxic after short term inhalation.

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

Skin corrosion/irritation

Not classified due to lack of data.

Components:

Thermolysin:

Result : Irritating to skin.
Remarks : May cause skin irritation in susceptible persons.

glycerol:

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

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Serious eye damage/eye irritation

Not classified due to lack of data.

Components:

Thermolysin:

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

glycerol:

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified due to lack of data.

Respiratory sensitisation

Not classified due to lack of data.

Components:

Thermolysin:

Assessment : May cause sensitisation by inhalation.

glycerol:

Assessment : Mild eye irritant
Mild respiratory irritant
No skin irritation

Germ cell mutagenicity

Not classified due to lack of data.

Components:

glycerol:

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

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

Carcinogenicity

Not classified due to lack of data.

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Components:

glycerol:

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
GLP : No information available.
Remarks : No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Not classified due to lack of data.

Components:

glycerol:

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

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

STOT - single exposure

Not classified due to lack of data.

Components:

Thermolysin:

Exposure routes : Inhalation
Assessment : May cause respiratory irritation.

STOT - repeated exposure

Not classified due to lack of data.

Components:

Thermolysin:

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

Repeated dose toxicity

Components:

glycerol:

Species : Rat, male and female

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NOAEL	:	4580 mg/kg
NOAEL	:	4.580 mg/kg
Application Route	:	Oral
Exposure time	:	90 d
Number of exposures	:	daily
Dose	:	4580 - 25,800 mg/kg/day
GLP	:	no
Species	:	Rat, male and female
Application Route	:	Inhalation
Test atmosphere	:	dust/mist
Exposure time	:	13 Weeks
Number of exposures	:	6 hours/day, 5 days/week
Dose	:	33, 165 and 660 mg/m ³
GLP	:	No information available.
Species	:	Rat
NOAEL	:	5040 mg/kg
NOAEL	:	5.040 mg/kg
Application Route	:	Dermal
Exposure time	:	45 Weeks
Number of exposures	:	8 hours/day, 5 days/week
Dose	:	0.5-4.0 ml/kg
GLP	:	no

Aspiration toxicity

Not classified due to lack of data.

Components:

Thermolysin:

No data available

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

Components:

Thermolysin:

Ecotoxicology Assessment

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

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Other organisms relevant to the environment : No data available

glycerol:

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

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

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

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

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

12.2 Persistence and degradability

Components:

glycerol:

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

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12.3 Bioaccumulative potential

Components:

Thermolysin:

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

glycerol:

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

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

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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

14.2 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**
If you intend to use this product as tattoo ink, please contact your

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	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 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: Class 3: 0,02 % hydrogen chloride 5.2.5: Organic Substances: Class 1: < 0,01 % Thermolysin 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

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Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Volatile organic compounds (VOC) content: 0,01 %

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.
Thermolysin

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

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : 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.
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
STOT SE : Specific target organ toxicity - single exposure
DE TRGS 900 : Germany. TRGS 900 - Occupational exposure limit values.
DE TRGS 900 / AGW : Time Weighted Average

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

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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

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 : KAPA2G Robust HotStart ReadyMix (2X)

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
Deutschland

Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-4223
E-mail address : info.dia-sds@roche.com

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH

Centre for detoxification: : Mainz +49(0)6131-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4 H302: Harmful if swallowed.

Specific target organ toxicity - single exposure, Category 2 H371: May cause damage to organs.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 Harmful if swallowed.
H371 May cause damage to organs.

Precautionary statements : **Prevention:**
P260 Do not breathe mist or vapours.

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P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P308 + P311 IF exposed or concerned: 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:

75-57-0 tetramethylammonium 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. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
tetramethylammonium chloride	75-57-0 200-880-8 01-2119970924-26	Acute Tox. 2; H300 Acute Tox. 3; H311 Skin Irrit. 2; H315 STOT SE 1; H370 (Central nervous system) <u>Aquatic Chronic 2;</u> H411 Acute toxicity estimate Acute oral toxicity: 47 mg/kg Acute dermal toxicity:	>= 1,0 - < 2,5

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		200,02 mg/kg	
Substances with a workplace exposure limit :			
glycerol	56-81-5 200-289-5 01-2119471987-18	Not classified	$\geq 10,0 - < 20,0$
dimethyl sulfoxide	67-68-5 200-664-3 01-2119431362-50	Not classified	$\geq 10,0 - < 20,0$

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.
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 : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do not 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

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.

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
Sulphur oxides
Nitrogen oxides (NO_x)
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.

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

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 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.

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

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. 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

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
glycerol	56-81-5	AGW (Inhalable fraction)	200 mg/m ³	DE TRGS 900
		Peak-limit: excursion factor (category): 2;(I)		
		Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child		
dimethyl sulfoxide	67-68-5	AGW	50 ppm 160 mg/m ³	DE TRGS 900
		Peak-limit: excursion factor (category): 2;(I)		
		Further information: Skin absorption, When there is compliance with the OEL and biological tolerance values, harm to the unborn child can not be excluded		

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

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Hand protection Material	:	Protective gloves
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.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Colour	:	colourless
Odour	:	odourless
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	:	does not flash
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)		
Solubility in other solvents	:	No data available

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

Vapour pressure : No data available

Relative density : No data available

Relative vapour density : 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.
The product is not flammable.

Self-ignition : Not applicable

Evaporation rate : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : 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 : No data available

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

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SECTION 11: Toxicological information

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

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: 1.906 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

tetramethylammonium chloride:

Acute oral toxicity : LD50 Oral (Rat): 47 mg/kg
Method: OECD Test Guideline 401
GLP: no

Acute dermal toxicity : LD50 Dermal (Rabbit): > 200 - < 500 mg/kg
Method: OECD Test Guideline 402
GLP: yes

glycerol:

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

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m³
Exposure time: 7 h
Test atmosphere: vapour
GLP: no
Assessment: The component/mixture is minimally toxic after short term inhalation.

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

dimethyl sulfoxide:

Acute oral toxicity : LD50 (Rat, male and female): 28.300 mg/kg
Method: OECD Test Guideline 401
GLP: no

Acute inhalation toxicity : LC0 (Rat, male and female): > 5,33 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: OECD Test Guideline 403
GLP: yes

Acute dermal toxicity : LD50 Dermal (Rat, male and female): 40.000 mg/kg
GLP: no

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Skin corrosion/irritation

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:

tetramethylammonium chloride:

Result : Irritating to skin.

glycerol:

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

dimethyl sulfoxide:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
GLP : yes
Remarks : Mild skin irritation

Serious eye damage/eye irritation

Components:

tetramethylammonium chloride:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

glycerol:

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

dimethyl sulfoxide:

Species : Rabbit
Exposure time : 24 h
Method : OECD Test Guideline 405
GLP : No information available.
Remarks : Mild eye irritation

Respiratory or skin sensitisation

Components:

tetramethylammonium chloride:

Test Type : Local lymph node assay (LLNA)
Species : Mouse

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Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 429

glycerol:

Assessment : Mild eye irritant
Mild respiratory irritant
No skin irritation

dimethyl sulfoxide:

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 429
GLP : No information available.

Assessment : Mild eye irritation
Mild skin irritation

Germ cell mutagenicity

Components:

tetramethylammonium chloride:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Result: negative

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Result: negative

glycerol:

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

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

dimethyl sulfoxide:

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

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Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: No information available.

Test Type: sister chromatid exchange assay
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 479
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Rat (male and female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Dose: 200, 1000, 5000 mg/kg/d
Method: OECD Test Guideline 474
GLP: yes

Carcinogenicity

Components:

glycerol:

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
GLP : No information available.
Remarks : No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

Components:

glycerol:

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

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

dimethyl sulfoxide:

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Effects on fertility : Species: Rat, male and female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Fertility: NOAEL: 1.000 mg/kg body weight
Method: OECD Test Guideline 421
GLP: yes

Effects on foetal development : Species: Rat, female
Application Route: Oral
Dose: 200, 1000, 5000 milligram per kilogram
Duration of Single Treatment: 10 d
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

STOT - single exposure

Components:

tetramethylammonium chloride:

Exposure routes : Ingestion
Target Organs : Central nervous system
Assessment : Causes damage to organs.

Repeated dose toxicity

Components:

tetramethylammonium chloride:

Species : Rat
NOAEL : 5 mg/kg
Application Route : Oral
Method : OECD Test Guideline 421
GLP : yes

glycerol:

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

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

Species : Rat
NOAEL : 5040 mg/kg

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

dimethyl sulfoxide:

Species : Monkey, male and female
NOAEL : 2970 mg/kg
NOAEL : 2.970 mg/kg
Application Route : Oral
Exposure time : 87 Weeks
Dose : 990, 2970, 8910 mg/kg
Method : OECD Test Guideline 452
GLP : no

Species : Rat, male and female
NOAEC : 2783 mg/l
Application Route : Inhalation
Test atmosphere : vapour
Exposure time : 13 Weeks
Dose : 0.310, 0.964, 2.783 mg/l
Method : OECD Test Guideline 413
GLP : yes

Species : Monkey, male and female
NOAEL : > 8910 mg/kg
NOAEL : > 8.910 mg/kg
Application Route : Dermal
Exposure time : 18 Months
Dose : 990, 2970, 8910 mg/kg bw/da
Method : OECD Test Guideline 452
GLP : no

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.

Further information

Components:

tetramethylammonium chloride:

Remarks : Other dangerous properties can not be excluded.

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SECTION 12: Ecological information

12.1 Toxicity

Components:

tetramethylammonium chloride:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 462 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0,16 mg/l
aquatic invertebrates : Exposure time: 11 d
GLP: yes

NOEC (Daphnia magna (Water flea)): 0,03 mg/l
Exposure time: 11 d
GLP: yes

LC50 (Daphnia magna (Water flea)): 1,86 mg/l
Exposure time: 48 h
GLP: yes

Toxicity to algae/aquatic : ErC50 (Pseudokirchneriella subcapitata (green algae)): 115
plants : mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

Ecotoxicology Assessment

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

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

Other organisms relevant to : No data available
the environment

glycerol:

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

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

Toxicity to algae/aquatic : (Scenedesmus quadricauda (Green algae)): > 10.000 mg/l
plants : End point: Growth rate

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Exposure time: 8 d
Test Type: static test
GLP: no

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

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

dimethyl sulfoxide:

Toxicity to fish : LC50 (*Danio rerio* (zebra fish)): > 25.000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 24.600 mg/l
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)): 17.000 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): 10 - 100 mg/l
Exposure time: 0,5 h
Analytical monitoring: no
Method: ISO 8192
GLP: No information available.

Ecotoxicology Assessment

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

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Other organisms relevant to the environment : No data available

12.2 Persistence and degradability

Components:

tetramethylammonium chloride:

Biodegradability : Remarks: Expected to be biodegradable

glycerol:

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

dimethyl sulfoxide:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge
Concentration: 2 mg/l
Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

12.3 Bioaccumulative potential

Components:

tetramethylammonium chloride:

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

glycerol:

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

dimethyl sulfoxide:

Partition coefficient: n-octanol/water : log Pow: -1,35 (20 °C)
pH: 7
GLP: No information available.

12.4 Mobility in soil

No data available

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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.

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

14.2 UN proper shipping name

14.3 Transport hazard class(es)

14.4 Packing group

14.5 Environmental hazards

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

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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 3
- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
- Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
- REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
- 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

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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: 10,02 %

Other regulations:

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

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

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

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

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

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

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

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

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

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

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

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

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

TSCA : All substances listed as active on the TSCA inventory

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

15.2 Chemical safety assessment

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

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SECTION 16: Other information

Full text of H-Statements

H300 : Fatal if swallowed.
H311 : Toxic in contact with skin.
H315 : Causes skin irritation.
H370 : Causes damage to organs if swallowed.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Skin Irrit. : Skin irritation
STOT SE : Specific target organ toxicity - single exposure
DE TRGS 900 : Germany. TRGS 900 - Occupational exposure limit values.
DE TRGS 900 / AGW : Time Weighted Average

Classification of the mixture:

Acute Tox. 4 H302
STOT SE 2 H371

Classification procedure:

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

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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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