

# cobas SARS-CoV-2 & Influenza A/B

Version Revision Date: Date of last issue: 08-20-2025 2.0 08-20-2025 Date of first issue: 04-24-2020

# **Cover letter for product:**

Trade name : cobas SARS-CoV-2 & Influenza A/B

Product code : 09211101190

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

- MMX-1
- MMX-3
- MMX-2
- INT CTL
- PROTEINASE K
- LIAT MAGNETIC PARTICLES
- R7 LYSIS BUFFER
- Wash Buffer
- Elution Buffer

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

#### **GHS** label elements

Hazard pictograms







Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary Statements : Prevention:

P261 Avoid breathing mist or vapors.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P272 Contaminated work clothing must not be allowed out of

the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

P285 In case of inadequate ventilation wear respiratory

protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON

CENTER/ doctor if you feel unwell. Rinse mouth.

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT

induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON



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CENTER/ doctor.

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

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

attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### Other hazards

None known.

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**

Product name : MMX-1

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road

Indianapolis, IN 46250

USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals

Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

## **GHS** label elements

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

#### Other hazards

None known.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)
Trehalose (D+)-), 2H2O	6138-23-4	>= 1 - < 5
Glycine, N,N'-1,2-ethanediylbis[N-	139-33-3	< 0.1
(carboxymethyl)-, sodium salt (1:2)		

Actual concentration is withheld as a trade secret

## **SECTION 4. FIRST AID MEASURES**

General advice : Do not leave the victim unattended.



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If inhaled : If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.

In case of eye contact : 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.

Most important symptoms and effects, both acute and

delayed

None known.

Notes to physician : Treat symptomatically.

## **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

Carbon oxides

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

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



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protective equipment and emergency procedures

Environmental precautions : If the product contaminates rivers and lakes or drains inform

respective authorities.

Methods and materials for containment and cleaning up

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

## **SECTION 7. HANDLING AND STORAGE**

Advice on protection against :

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling : For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Conditions for safe storage : Electrical installations / working materials must comply with

the technological safety standards.

Further information on

storage conditions

See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on

storage stability

No decomposition if stored and applied as directed.

## **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Glycine, N,N'-1,2- ethanediylbis[N- (carboxymethyl)-, sodium salt (1:2) The value is given in analogy to the following substances: Edetic acid	139-33-3	IOEL	1.5 mg/m3	Roche Industrial Hygiene Committee (RIHC)

**Engineering measures** : No data available

## Personal protective equipment

Hand protection

In case of full contact:

Material : Nitrile rubber



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Break through time : > 480 min Glove thickness : > 0.4 mm

In case of contact through splashing:

Material : Nitrile rubber

Break through time : 60 min

Glove thickness : 0.11 - 0.2 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : General industrial hygiene practice.

# **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available



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Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 0.9943 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle Size Distribution : Not applicable

## **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : Strong oxidizing agents

Not applicable

Hazardous decomposition

products

No data available

No hazardous decomposition products are known.



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#### **SECTION 11. TOXICOLOGICAL INFORMATION**

## **Acute toxicity**

Not classified due to lack of data.

## **Components:**

Trehalose (D+)-), 2H2O:

Acute oral toxicity : LD50 (Rat): 16,000 mg/kg

# Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 - 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1 - < 5 mg/l

Exposure time: 6 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The component/mixture is moderately toxic after

short term inhalation.

#### Skin corrosion/irritation

Not classified due to lack of data.

#### **Components:**

## Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No skin irritation

# Serious eye damage/eye irritation

Not classified due to lack of data.

# **Components:**

# Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No eye irritation

#### Respiratory or skin sensitization

#### Skin sensitization

Not classified due to lack of data.

## Respiratory sensitization

Not classified due to lack of data.

## **Components:**

## Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Test Type : Maximization Test

Species : Guinea pig



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Assessment : Does not cause skin sensitization.

Method : OECD Test Guideline 406

## Germ cell mutagenicity

Not classified due to lack of data.

# Carcinogenicity

Not classified due to lack of data.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

## 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:**

## Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Routes of exposure : inhalation (dust/mist/fume)

Target Organs : Respiratory Tract

Assessment : May cause damage to organs through prolonged or repeated

exposure.

# **Aspiration toxicity**

Not classified due to lack of data.

#### **Further information**

**Product:** 

Remarks : No data available

## **SECTION 12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

## **Components:**

# Trehalose (D+)-), 2H2O:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h Test Type: static test

MMX-1



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Toxicity to fish (Chronic

toxicity)

NOEC (Danio rerio (zebra fish)): 100 mg/l

Exposure time: 96 d

**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

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l

Exposure time: 96 h Test Type: static test

Remarks: nominal concentration Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h Test Type: static test Method: DIN 38412

Remarks: nominal concentration

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h Test Type: static test

Remarks: Based on data from similar materials

Toxicity to fish (Chronic

toxicity)

NOEC (Danio rerio (zebra fish)): >= 36.9 mg/l

Exposure time: 35 d

Test Type: flow-through test Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC20 (activated sludge): > 500 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Persistence and degradability

**Components:** 

Trehalose (D+)-), 2H2O:

Biodegradability : aerobic

Inoculum: activated sludge, non-adapted

Biochemical oxygen demand Result: Readily biodegradable.

Biodegradation: 73 %



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Method: OECD Test Guideline 301A

Remarks: The 10 day time window criterion is not fulfilled.

aerobic

Inoculum: activated sludge, non-adapted

Dissolved organic carbon (DOC) Result: Readily biodegradable.

Biodegradation: 98 %

Method: OECD Test Guideline 301A

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Biodegradability aerobic

> Result: Not readily biodegradable. Method: OECD Test Guideline 301D

Remarks: Based on data from similar materials

Bioaccumulative potential

**Components:** 

Trehalose (D+)-), 2H2O:

Partition coefficient: n-

octanol/water

: Remarks: No data available

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Bioaccumulation Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 1.8

Exposure time: 28 d

Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-

log Pow: -4.3 (77 °F / 25 °C)

octanol/water

pH: 4.5

Mobility in soil No data available

Other adverse effects

**Product:** 

Ozone-Depletion Potential Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

Additional ecological

information

No data available

MMX-1 11



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#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : 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.

#### **SECTION 14. TRANSPORT INFORMATION**

## **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

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

Not applicable

**Domestic regulation** 

**49 CFR** 

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

#### **SECTION 15. REGULATORY INFORMATION**

# **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

## SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.



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#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

#### **Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

#### **US State Regulations**

## Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

## Pennsylvania Right To Know

Water 7732-18-5

## Maine Chemicals of High Concern

Product does not contain any listed chemicals

# **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

#### **Washington Chemicals of High Concern**

Product does not contain any listed chemicals

#### The ingredients 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.

NOTUPDATED\_2'-Deoxyguanosine 5'-triphosphate sodium

salt

NOTUPDATED\_Uridine 5'-(tetrahydrogen triphosphate), 2'-

deoxy-, disodium salt

**Glycols** 

2'-Deoxycytidine 5'-triphosphate disodium salt

Modified alkyl carboxylate



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2'-Deoxyguanosine 5'-(trihydrogen diphosphate)

NOTUPDATED\_2'-Deoxyadenosine-5'-diphosphate

Uridine, 2'-deoxy-, 5'-(trihydrogen pyrophosphate)

Primer / Oligonucleotide / Probe

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

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

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

TECI: Not in compliance with the inventory

# **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

#### **SECTION 16. OTHER INFORMATION**

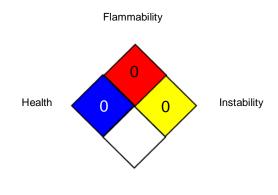
# **Further information**



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#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL -Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS -Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand



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Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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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.

US / Z8 / 2404



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#### **SECTION 1. IDENTIFICATION**

Product name : MMX-3

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road

Indianapolis, IN 46250

USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals

Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

## **GHS** label elements

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

#### Other hazards

None known.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)
Trehalose (D+)-), 2H2O	6138-23-4	>= 20 - < 30
1,3-Propanediol, 2-amino-2- (hydroxymethyl)-, hydrochloride (1:1)	1185-53-1	>= 1 - < 5
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2)	139-33-3	< 0.1

Actual concentration is withheld as a trade secret

#### **SECTION 4. FIRST AID MEASURES**



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General advice : Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.

In case of eye contact : 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.

Most important symptoms and effects, both acute and

delayed

None known.

Notes to physician : Treat symptomatically.

# **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

Carbon oxides

Nitrogen oxides (NOx)

Gaseous hydrogen chloride (HCI).

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment:

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**



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Personal precautions, protective equipment and emergency procedures

Refer to protective measures listed in sections 7 and 8.

Environmental precautions

If the product contaminates rivers and lakes or drains inform

respective authorities.

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

#### **SECTION 7. HANDLING AND STORAGE**

Advice on protection against :

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Conditions for safe storage Electrical installations / working materials must comply with

the technological safety standards.

Further information on

storage conditions

See label, package insert or internal guidelines

Materials to avoid No materials to be especially mentioned.

Further information on

storage stability

No decomposition if stored and applied as directed.

## **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Glycine, N,N'-1,2- ethanediylbis[N- (carboxymethyl)-, sodium salt (1:2) The value is given in analogy to the following substances: Edetic acid	139-33-3	IOEL	1.5 mg/m3	Roche Industrial Hygiene Committee (RIHC)

**Engineering measures** No data available

#### Personal protective equipment

Hand protection

In case of full contact:

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Material : Nitrile rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

In case of contact through splashing:

Material : Nitrile rubber

Break through time : 60 min

Glove thickness : 0.11 - 0.2 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : General industrial hygiene practice.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 8.5

Concentration: 100 %

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available



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Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density: 1.037 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle Size Distribution : Not applicable

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : Strong oxidizing agents

Not applicable

Hazardous decomposition : No data available



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products

No hazardous decomposition products are known.

## **SECTION 11. TOXICOLOGICAL INFORMATION**

#### **Acute toxicity**

Not classified due to lack of data.

# **Components:**

Trehalose (D+)-), 2H2O:

Acute oral toxicity : LD50 (Rat): 16,000 mg/kg

## 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Acute oral toxicity : LD50 (Rat, female): > 5,000 mg/kg

Method: OECD Test Guideline 425

GLP: yes

Acute dermal toxicity : LD50 (Rat, male and female): > 5,000 mg/kg

Method: OECD Test Guideline 402

Remarks: No mortality observed at this dose.

## Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 - 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1 - < 5 mg/l

Exposure time: 6 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The component/mixture is moderately toxic after

short term inhalation.

#### Skin corrosion/irritation

Not classified due to lack of data.

#### **Components:**

# 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Species : human keratinocytes

Exposure time : 42 min

Method : OECD Test Guideline 439

Result : No skin irritation

GLP : yes



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## Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified due to lack of data.

#### Components:

# 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Species : Bovine cornea Result : No eye irritation

Exposure time : 240 min

Method : OECD Test Guideline 437

GLP : yes

#### Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No eye irritation

#### Respiratory or skin sensitization

## Skin sensitization

Not classified due to lack of data.

## Respiratory sensitization

Not classified due to lack of data.

## **Components:**

# 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Test Type : Maximization Test

Species : Guinea pig

Assessment : Does not cause skin sensitization.

Method : OECD Test Guideline 406

GLP : yes

# Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Test Type : Maximization Test

Species : Guinea pig

Assessment : Does not cause skin sensitization.

Method : OECD Test Guideline 406

#### Germ cell mutagenicity

Not classified due to lack of data.



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#### Components:

## 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

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: Microbial mutagenesis assay (Ames test)

Test system: Escherichia coli

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative GLP: yes

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative GLP: yes

Test Type: Chromosome aberration test in vitro

Test system: Chinese hamster lung cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 473

Result: negative

GLP: yes

# Carcinogenicity

Not classified due to lack of data.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

# Reproductive toxicity

Not classified due to lack of data.

#### **Components:**

## 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Effects on fertility : Species: Rat, male and female

Application Route: Oral

Dose: 100, 300, 1000 mg/kg bw/day Duration of Single Treatment: 54 d

General Toxicity F1: NOAEL: > 1,000 mg/kg body weight



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> Method: OECD Test Guideline 421 Result: No effects on fertility.

GLP: yes

## STOT-single exposure

Not classified due to lack of data.

#### STOT-repeated exposure

Not classified due to lack of data.

#### **Components:**

# Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

: inhalation (dust/mist/fume) Routes of exposure

Target Organs Respiratory Tract

May cause damage to organs through prolonged or repeated Assessment

exposure.

# Repeated dose toxicity

#### **Components:**

## 1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

**Species** Rat, male and female

**NOAEL** > 1000 mg/kg

Application Route Oral Exposure time 54 d

100, 300, 1000 mg/kg bw/day Dose Method **OECD Test Guideline 421** 

GLP yes

# **Aspiration toxicity**

Not classified due to lack of data.

#### **Further information**

**Product:** 

Remarks : No data available

## **SECTION 12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

# **Components:**

Trehalose (D+)-), 2H2O:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

> Exposure time: 96 h Test Type: static test

Toxicity to fish (Chronic

: NOEC (Danio rerio (zebra fish)): 100 mg/l

Exposure time: 96 d toxicity)

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**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

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 460 mg/l

End point: mortality Exposure time: 96 h Test Type: static test Analytical monitoring: no

Method: OECD Test Guideline 203 GLP: No information available.

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 117 mg/l

End point: Immobilization Exposure time: 48 h Test Type: static test Analytical monitoring: yes

Method: OECD Test Guideline 202

GLP: yes

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 397

mg/

Exposure time: 72 h
Test Type: static test
Analytical monitoring: no

Method: OECD Test Guideline 201 GLP: No information available.

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l

Exposure time: 3 h
Test Type: static test
Analytical monitoring: no

Method: OECD Test Guideline 209

GLP: yes

**Ecotoxicology Assessment** 

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

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

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

Other organisms relevant to

the environment

No data available



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Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l

Exposure time: 96 h Test Type: static test

Remarks: nominal concentration Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h Test Type: static test Method: DIN 38412

Remarks: nominal concentration

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h Test Type: static test

Remarks: Based on data from similar materials

Toxicity to fish (Chronic

toxicity)

NOEC (Danio rerio (zebra fish)): >= 36.9 mg/l

Exposure time: 35 d
Test Type: flow-through test

Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC20 (activated sludge): > 500 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Persistence and degradability

**Components:** 

Trehalose (D+)-), 2H2O:

Biodegradability : aerobic

Inoculum: activated sludge, non-adapted

Biochemical oxygen demand Result: Readily biodegradable.

Biodegradation: 73 %

Method: OECD Test Guideline 301A

Remarks: The 10 day time window criterion is not fulfilled.

aerobic

Inoculum: activated sludge, non-adapted

Dissolved organic carbon (DOC) Result: Readily biodegradable.

Biodegradation: 98 %

Method: OECD Test Guideline 301A

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Biodegradability : aerobic

Inoculum: activated sludge, non-adapted

Concentration: 30 mg/l



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Result: Readily biodegradable. Biodegradation: 97.1 %

Exposure time: 28 d

Method: OECD Test Guideline 301F

GLP: yes

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Biodegradability : aerobic

Result: Not readily biodegradable. Method: OECD Test Guideline 301D

Remarks: Based on data from similar materials

Bioaccumulative potential

**Components:** 

Trehalose (D+)-), 2H2O:

Partition coefficient: n-

octanol/water

Remarks: No data available

1,3-Propanediol, 2-amino-2-(hydroxymethyl)-, hydrochloride (1:1):

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water,

accumulation in organisms is not expected.

Partition coefficient: n-

octanol/water

log Pow: -3.6 (68 °F / 20 °C)

pH: 5 - 7

Method: OECD Test Guideline 107

GLP: no

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 1.8

Exposure time: 28 d

Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-

: log Pow: -4.3 (77 °F / 25 °C) pH: 4.5

octanol/water

Mobility in soil
No data available

Other adverse effects

**Product:** 

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).



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Additional ecological

information

: No data available

## **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : 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.

#### **SECTION 14. TRANSPORT INFORMATION**

## International Regulations

**UNRTDG** 

Not regulated as a dangerous good

**IATA-DGR** 

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

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

Not applicable

**Domestic regulation** 

**49 CFR** 

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

## **SECTION 15. REGULATORY INFORMATION**

## **CERCLA Reportable Quantity**

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

# SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards



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SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

#### **Clean Water Act**

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Glycine, N,N'-1,2- 60-00-4 >= 0 - < 0.1 %

ethanediylbis[N-(carboxymethyl)-

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Glycine, N,N'-1,2- 60-00-4 >= 0 - < 0.1 %

ethanediylbis[N-(carboxymethyl)-

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

# **US State Regulations**

#### **Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

## Pennsylvania Right To Know

Water 7732-18-5
Trehalose (D+)-), 2H2O 6138-23-4
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)- 60-00-4

# **Maine Chemicals of High Concern**

Product does not contain any listed chemicals

#### **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

## **Washington Chemicals of High Concern**

Product does not contain any listed chemicals

# The ingredients 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.



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Glycols

Modified alkyl carboxylate

Primer / Oligonucleotide / Probe

Taq DNA Polymerase

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

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

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

TECI: Not in compliance with the inventory

# **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

## **SECTION 16. OTHER INFORMATION**

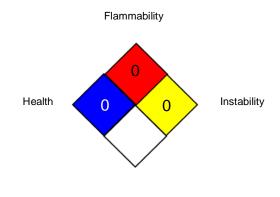
# **Further information**



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#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL -Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS -Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand



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Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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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.

US / Z8 / 2404



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#### **SECTION 1. IDENTIFICATION**

Product name : MMX-2

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

Indianapolis, IN 46250

USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals

Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

## **GHS** label elements

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

#### Other hazards

None known.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)
1,2,3-Propanetriol	56-81-5	>= 1 - < 5

Actual concentration is withheld as a trade secret

## **SECTION 4. FIRST AID MEASURES**

General advice : Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical

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advice.

If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.

In case of eye contact : 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.

Most important symptoms and effects, both acute and

delayed

None known.

Notes to physician : Treat symptomatically.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

Carbon oxides

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

## **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures Refer to protective measures listed in sections 7 and 8.

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Environmental precautions : If the product contaminates rivers and lakes or drains inform

respective authorities.

Methods and materials for

containment and cleaning up

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

**SECTION 7. HANDLING AND STORAGE** 

Advice on protection against :

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling : For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Conditions for safe storage : Electrical installations / working materials must comply with

the technological safety standards.

Further information on

storage conditions

See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on

storage stability

No decomposition if stored and applied as directed.

# **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,2,3-Propanetriol	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (mist, total dust)	15 mg/m3	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m3	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m3	OSHA P0

**Engineering measures** : No data available

Personal protective equipment

Hand protection

In case of full contact:

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Material : Nitrile rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

In case of contact through splashing:

Material : Nitrile rubber

Break through time : 60 min

Glove thickness : 0.11 - 0.2 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : General industrial hygiene practice.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 7.5

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower : No data available



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flammability limit

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 0.9943 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle Size Distribution : Not applicable

## **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : Strong oxidizing agents

Not applicable

Hazardous decomposition

products

No data available



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No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

## **Acute toxicity**

Not classified due to lack of data.

## **Components:**

## 1,2,3-Propanetriol:

Acute oral toxicity : LC50 (Mouse): 11,500 mg/kg

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

Exposure time: 7 h
Test atmosphere: vapor

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:**

# 1,2,3-Propanetriol:

Species : Rabbit Exposure time : 24 h

Result : No skin irritation

GLP : no

## Serious eye damage/eye irritation

Not classified due to lack of data.

## **Components:**

## 1,2,3-Propanetriol:

Species : Rabbit

Result : No eye irritation

Exposure time : 7 d GLP : no

## Respiratory or skin sensitization

#### Skin sensitization

Not classified due to lack of data.

## Respiratory sensitization

Not classified due to lack of data.



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## **Components:**

1,2,3-Propanetriol:

Assessment : Mild eye irritant, Mild respiratory irritant, No skin irritation

Germ cell mutagenicity

Not classified due to lack of data.

**Components:** 

1,2,3-Propanetriol:

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.

**Components:** 

1,2,3-Propanetriol:

Species : Rat, male and female

Application Route : Oral Exposure time : 2 Years

GLP : No information available.

Remarks : No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified due to lack of data.

**Components:** 

1,2,3-Propanetriol:

Effects on fertility : Test Type: Two-generation study



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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 fetal 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.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

**Components:** 

1,2,3-Propanetriol:

Species : Rat, male and female

NOAEL : 4580 mg/kg NOAEL : 4,580 mg/kg

Application Route : Oral Exposure time : 90 d Number of exposures : daily

Dose : 4580 - 25,800 mg/kg/day

GLP : no

Species : Rat, male and female

Application Route : Inhalation Test atmosphere : dust/mist Exposure time : 13 Weeks

Number of exposures : 6 hours/day, 5 days/week
Dose : 33, 165 and 660 mg/m3
GLP : No information available.

Species : Rat

NOAEL : 5040 mg/kg
NOAEL : 5,040 mg/kg
Application Route : Dermal
Exposure time : 45 Weeks

Number of exposures : 8 hours/day, 5 days/week

Dose : 0.5-4.0 ml/kg

GLP : no

Repeated dose toxicity -

Assessment

: Mild eye irritant, Mild respiratory irritant, No skin irritation



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**Aspiration toxicity** 

Not classified due to lack of data.

**Further information** 

**Product:** 

Remarks : No data available

#### **SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity** 

**Components:** 

1,2,3-Propanetriol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l

End point: mortality Exposure time: 96 h Test Type: static test

End point: mortality

GLP: no

Toxicity to daphnia and other :

aquatic invertebrates

LC50 (Daphnia magna (Water flea)): 1,955 mg/l

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



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## Persistence and degradability

**Components:** 

1,2,3-Propanetriol:

Biodegradability aerobic

> Inoculum: activated sludge Concentration: 226 mg/l Result: Readily biodegradable.

Biodegradation: 94 % Exposure time: 24 h

GLP: no

Bioaccumulative potential

**Components:** 

1,2,3-Propanetriol:

Partition coefficient: n-

log Pow: -1.75 (77 °F / 25 °C) octanol/water

pH: 7.4

Method: OECD Test Guideline 107

GLP: no

Mobility in soil

No data available

Other adverse effects **Product:** 

Ozone-Depletion Potential Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).

Additional ecological

information

No data available

## **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues Can be disposed as waste water, when in compliance with

local regulations.

Empty containers should be taken to an approved waste Contaminated packaging

handling site for recycling or disposal.

## **SECTION 14. TRANSPORT INFORMATION**

## International Regulations

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#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

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

Not applicable

#### **Domestic regulation**

#### 49 CFR

Not regulated as a dangerous good

## Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

#### **SECTION 15. REGULATORY INFORMATION**

### **CERCLA Reportable Quantity**

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

## SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

1,2,3-Propanetriol 56-81-5 >= 1 - < 5 %

#### **Clean Water Act**

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:



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Glycine, N,N'-1,2- 60-00-4 >= 0.1 - < 1 %

ethanediylbis[N-(carboxymethyl)-

Hydrochloric acid 7647-01-0 >= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table

117.3:

Glycine, N,N'-1,2- 60-00-4 >= 0.1 - < 1 %

ethanediylbis[N-(carboxymethyl)-

Hydrochloric acid 7647-01-0 >= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section

307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

# **US State Regulations**

Massachusetts Right To Know

1,2,3-Propanetriol 56-81-5 Hydrochloric acid 56-81-0

Pennsylvania Right To Know

Water 7732-18-5
1,2,3-Propanetriol 56-81-5
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)Hydrochloric acid 7647-01-0

**Maine Chemicals of High Concern** 

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern** 

Product does not contain any listed chemicals

**Washington Chemicals of High Concern** 

Product does not contain any listed chemicals

**California Permissible Exposure Limits for Chemical Contaminants** 

1,2,3-Propanetriol 56-81-5

The ingredients 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.

Reverse Transcriptase

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



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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

#### **TSCA list**

The following substance(s) is/are subject to a Significant New Use Rule:

Poly(oxy-1,2-ethanediyl), .alpha.- 9016-45-9 See 40 CFR § 721.10765; Proposed

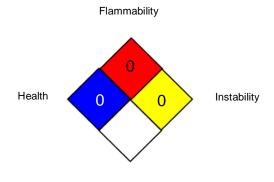
(nonylphenyl)-.omega.-hydroxy-

No substances are subject to TSCA 12(b) export notification requirements.

#### **SECTION 16. OTHER INFORMATION**

#### **Further information**

### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated

values)

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1

Limits for Air Contaminants

OSHA P0 / TWA : 8-hour time weighted average OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response,



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Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL -Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS -Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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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.

US / Z8 / 2404



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#### **SECTION 1. IDENTIFICATION**

Product name : INT CTL

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

Indianapolis, IN 46250

USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals

Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

## **GHS** label elements

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

#### Other hazards

None known.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)
Poly(oxy-1,2-ethanediyl), .alpha	25322-68-3	>= 30 - < 50
hydroomegahydroxy-		
Ribonuclease	9001-99-4	< 0.1

Actual concentration is withheld as a trade secret

## **SECTION 4. FIRST AID MEASURES**

General advice : Do not leave the victim unattended.



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If inhaled : If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.

In case of eye contact : 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.

Most important symptoms and effects, both acute and

delayed

None known.

Notes to physician : Treat symptomatically.

## **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

Carbon oxides

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

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



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protective equipment and emergency procedures

Environmental precautions : If the product contaminates rivers and lakes or drains inform

respective authorities.

Methods and materials for containment and cleaning up

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

**SECTION 7. HANDLING AND STORAGE** 

Advice on protection against :

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling : For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Conditions for safe storage : Electrical installations / working materials must comply with

the technological safety standards.

Further information on

storage conditions

See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on

storage stability

No decomposition if stored and applied as directed.

# **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Poly(oxy-1,2-ethanediyl), .alphahydroomega hydroxy-	25322-68-3	TWA (aerosol)	10 mg/m3	US WEEL
Ribonuclease	9001-99-4	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

**Engineering measures** : No data available

Personal protective equipment

Hand protection

In case of full contact:



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Material : Nitrile rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

In case of contact through splashing:

Material : Nitrile rubber

Break through time : 60 min

Glove thickness : 0.11 - 0.2 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : General industrial hygiene practice.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower : No data available



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flammability limit

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.062 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle Size Distribution : Not applicable

## **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : Strong oxidizing agents

Not applicable

Hazardous decomposition

products

No data available



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No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

## **Acute toxicity**

Not classified due to lack of data.

## **Components:**

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Acute oral toxicity : LD50 Oral (Rat): 22,000 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): > 20,000 mg/kg

Ribonuclease:

Acute oral toxicity : Acute toxicity estimate: > 5,001 mg/kg

Method: Expert judgment

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l

Test atmosphere: dust/mist Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg

Method: Expert judgment

#### Skin corrosion/irritation

Not classified due to lack of data.

## **Components:**

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Remarks : This information is not available.

## Serious eye damage/eye irritation

Not classified due to lack of data.

# **Components:**

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Remarks : This information is not available.

# Respiratory or skin sensitization

#### Skin sensitization

Not classified due to lack of data.

## Respiratory sensitization

Not classified due to lack of data.



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## Germ cell mutagenicity

Not classified due to lack of data.

# Carcinogenicity

Not classified due to lack of data.

## **Components:**

#### Ribonuclease:

Remarks : No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

## Reproductive toxicity

Not classified due to lack of data.

#### STOT-single exposure

Not classified due to lack of data.

#### **Components:**

## Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

## Ribonuclease:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

# STOT-repeated exposure

Not classified due to lack of data.

# Components:

## Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.



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Ribonuclease:

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:** 

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

No data available

Ribonuclease:

No data available

**Further information** 

**Product:** 

Remarks : No data available

**SECTION 12. ECOLOGICAL INFORMATION** 

**Ecotoxicity** 

**Components:** 

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

: > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 201

**Ecotoxicology Assessment** 

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

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

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

Other organisms relevant to

the environment

No data available



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Ribonuclease:

Toxicity to fish : LC50 :> 100 mg/l

Exposure time: 96 h

**Ecotoxicology Assessment** 

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

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

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

Other organisms relevant to

the environment

: No data available

Persistence and degradability

No data available

**Bioaccumulative potential** 

**Components:** 

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Partition coefficient: n-

octanol/water

: Remarks: No data available

Ribonuclease:

Partition coefficient: n-

octanol/water

: Remarks: No data available

Mobility in soil

No data available

Other adverse effects

**Product:** 

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).

Additional ecological

information

: No data available

**Components:** 

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Adsorbed organic bound : Remarks: Not applicable



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halogens (AOX)

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : 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.

#### **SECTION 14. TRANSPORT INFORMATION**

## **International Regulations**

**UNRTDG** 

Not regulated as a dangerous good

**IATA-DGR** 

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

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

Not applicable

**Domestic regulation** 

**49 CFR** 

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

## **SECTION 15. REGULATORY INFORMATION**

#### **CERCLA Reportable Quantity**

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

## SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.



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#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

Poly(oxy-1,2-ethanediyl), 25322-68-3

>= 30 - < 50 %

.alpha.-hydro-.omega.-

hydroxy-

#### **Clean Water Act**

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Glycine, N,N'-1,2- 60-00-4 >= 0 - < 0.1 %

ethanediylbis[N-(carboxymethyl)-

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Glycine, N,N'-1,2- 60-00-4 >= 0 - < 0.1 %

ethanediylbis[N-(carboxymethyl)-

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

## **US State Regulations**

## Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

## Pennsylvania Right To Know

Water 7732-18-5
Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxyGlycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)- 60-00-4

#### **Maine Chemicals of High Concern**

Product does not contain any listed chemicals

#### **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

## **Washington Chemicals of High Concern**

Product does not contain any listed chemicals

## The ingredients 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.

Glycols



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NOTUPDATED\_Proprietary Ingredients, non hazardous

Modified alkyl carboxylate

Ribonuclease

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

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

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

TECI: Not in compliance with the inventory

# **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

#### **SECTION 16. OTHER INFORMATION**

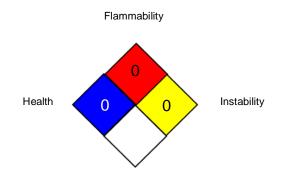
**Further information** 



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#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)

US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL -Domestic Substances List (Canada): ECx - Concentration associated with x% response: EHS -Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-



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Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 08-20-2025

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.

US / Z8 / 2404



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#### **SECTION 1. IDENTIFICATION**

Product name : PROTEINASE K

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

Indianapolis, IN 46250

USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals

Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Respiratory sensitization : Category 1

Skin sensitization Category 1

**GHS** label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Precautionary Statements : Prevention:

P261 Avoid breathing mist or vapors.

P272 Contaminated work clothing must not be allowed out of

the workplace.

P280 Wear protective gloves.

P285 In case of inadequate ventilation wear respiratory



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protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

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

attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### Other hazards

None known.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
1,2,3-Propanetriol	56-81-5	>= 30 - < 50
Proteinase K	39450-01-6	>= 0.1 - < 1
Glycine, N,N'-1,2-ethanediylbis[N-	139-33-3	< 0.1
(carboxymethyl)-, sodium salt (1:2)		

Actual concentration is withheld as a trade secret

#### **SECTION 4. FIRST AID MEASURES**

General advice : Move out of dangerous area.

Show this material safety data sheet to the doctor in

attendance.

Do not leave the victim unattended.

If inhaled : Call a physician or poison control center immediately.

If unconscious, place in recovery position and seek medical

advice.

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

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.



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Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician. Take victim immediately to hospital.

Most important symptoms and effects, both acute and

delayed

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Notes to physician : Treat symptomatically.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

Carbon oxides

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment:

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures Use personal protective equipment.

Ensure adequate ventilation.

Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Prevent product from entering drains.

Prevent further leakage or spillage if safe to do so.

If the product contaminates rivers and lakes or drains inform

respective authorities.

Methods and materials for containment and 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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#### **SECTION 7. HANDLING AND STORAGE**

Advice on protection against :

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling : Avoid formation of aerosol.

Do not breathe vapors/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. Dispose of rinse water in accordance with local and national

regulations.

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

used.

Conditions for safe storage : 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

Further information on

storage stability

No decomposition if stored and applied as directed.

## **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,2,3-Propanetriol	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (mist, total dust)	15 mg/m3	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m3	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m3	OSHA P0
Proteinase K	39450-01-6	IOEL	0.00006 mg/m3	Roche Industrial



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				Hygiene Committee (RIHC)
Glycine, N,N'-1,2- ethanediylbis[N- (carboxymethyl)-, sodium salt (1:2) The value is given in analogy to the following substances: Edetic acid	139-33-3	IOEL	1.5 mg/m3	Roche Industrial Hygiene Committee (RIHC)

**Engineering measures** : No data available

## Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

In case of full contact:

Material : Nitrile rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

In case of contact through splashing:

Material : Nitrile rubber

Break through time : 60 min

Glove thickness : 0.11 - 0.2 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Skin and body protection : Impervious clothing

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

Hygiene measures : Wash hands before breaks and at the end of workday.

# SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES



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Appearance : liquid

Color : colorless

Odor : No data available

Odor Threshold : No data available

pH : 7.5

Concentration: 100 %

Melting point/ range :  $< -85 \, ^{\circ}\text{F} / < -65 \, ^{\circ}\text{C}$ 

Boiling point/boiling range : 210 °F / 99 °C

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.126 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

: No data available

Autoignition temperature : No data available



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Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle Size Distribution : Not applicable

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

No decomposition if stored and applied as directed.

Conditions to avoid : No data available

Incompatible materials : Not applicable

Hazardous decomposition

products

No hazardous decomposition products are known.

## **SECTION 11. TOXICOLOGICAL INFORMATION**

## **Acute toxicity**

Not classified due to lack of data.

# **Components:**

1,2,3-Propanetriol:

Acute oral toxicity : LC50 (Mouse): 11,500 mg/kg

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

Exposure time: 7 h
Test atmosphere: vapor

GLP: no

Assessment: The component/mixture is minimally toxic after

short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg

GLP: no



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# Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 - 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1 - < 5 mg/l

Exposure time: 6 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The component/mixture is moderately toxic after

short term inhalation.

## Skin corrosion/irritation

Not classified due to lack of data.

**Product:** 

Remarks : May cause skin irritation and/or dermatitis.

**Components:** 

1,2,3-Propanetriol:

Species : Rabbit Exposure time : 24 h

Result : No skin irritation

GLP : no

**Proteinase K:** 

Result : Irritating to skin.

Remarks : May cause skin irritation and/or dermatitis.

## Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No skin irritation

# Serious eye damage/eye irritation

Not classified due to lack of data.

**Product:** 

Remarks : Vapors may cause irritation to the eyes, respiratory system

and the skin.

**Components:** 

1,2,3-Propanetriol:

Species : Rabbit



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Result : No eye irritation

Exposure time : 7 d GLP : no

**Proteinase K:** 

Result : Irritating to eyes.

Remarks : May cause irreversible eye damage.

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

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

**Product:** 

Remarks : Causes sensitization.

**Components:** 

1,2,3-Propanetriol:

Assessment : Mild eye irritant, Mild respiratory irritant, No skin irritation

Proteinase K:

Assessment : May cause sensitization by skin contact.

Remarks : Causes sensitization.

Assessment : May cause sensitization by inhalation.

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Test Type : Maximization Test

Species : Guinea pig

Assessment : Does not cause skin sensitization.

Method : OECD Test Guideline 406



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## Germ cell mutagenicity

Not classified due to lack of data.

## **Components:**

## 1,2,3-Propanetriol:

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.

#### **Components:**

## 1,2,3-Propanetriol:

Species : Rat, male and female

Application Route : Oral Exposure time : 2 Years

GLP : No information available.

Remarks : No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

# Reproductive toxicity

Not classified due to lack of data.

## **Components:**

# 1,2,3-Propanetriol:

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



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Effects on fetal 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:** 

Proteinase K:

Assessment : May cause respiratory irritation.

STOT-repeated exposure

Not classified due to lack of data.

**Components:** 

**Proteinase K:** 

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Routes of exposure : inhalation (dust/mist/fume)

Target Organs : Respiratory Tract

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

**Components:** 

1,2,3-Propanetriol:

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



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Dose : 33, 165 and 660 mg/m3 GLP : No information available.

Species : Rat

NOAEL : 5040 mg/kg
NOAEL : 5,040 mg/kg
Application Route : Dermal
Exposure time : 45 Weeks

Number of exposures : 8 hours/day, 5 days/week

Dose : 0.5-4.0 ml/kg

GLP : no

Repeated dose toxicity -

Assessment

: Mild eye irritant, Mild respiratory irritant, No skin irritation

### **Aspiration toxicity**

Not classified due to lack of data.

### **Components:**

# Proteinase K:

No data available

#### **Further information**

**Product:** 

Remarks : No data available

### **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

### **Components:**

# 1,2,3-Propanetriol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l

End point: mortality Exposure time: 96 h Test Type: static test

End point: mortality

GLP: no

Toxicity to daphnia and other :

aquatic invertebrates

LC50 (Daphnia magna (Water flea)): 1,955 mg/l

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



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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

**Proteinase K:** 

**Ecotoxicology Assessment** 

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

Other organisms relevant to

the environment

: No data available

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l

Exposure time: 96 h Test Type: static test

Remarks: nominal concentration Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h Test Type: static test Method: DIN 38412

Remarks: nominal concentration

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h Test Type: static test

Remarks: Based on data from similar materials

Toxicity to fish (Chronic

toxicity)

NOEC (Danio rerio (zebra fish)): >= 36.9 mg/l

Exposure time: 35 d

Test Type: flow-through test

Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC20 (activated sludge): > 500 mg/l

Exposure time: 30 min



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Method: OECD Test Guideline 209

### Persistence and degradability

# **Components:**

# 1,2,3-Propanetriol:

Biodegradability : aerobic

Inoculum: activated sludge Concentration: 226 mg/l Result: Readily biodegradable.

Biodegradation: 94 % Exposure time: 24 h

GLP: no

# Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Biodegradability : aerobic

Result: Not readily biodegradable. Method: OECD Test Guideline 301D

Remarks: Based on data from similar materials

# Bioaccumulative potential

#### **Components:**

#### 1,2,3-Propanetriol:

Partition coefficient: n- : log Pow: -1.75 (77 °F / 25 °C)

octanol/water pH: 7.4

Method: OECD Test Guideline 107

GLP: no

**Proteinase K:** 

Partition coefficient: n-

octanol/water

Remarks: No data available

### Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 1.8

Exposure time: 28 d

Remarks: Bioaccumulation is unlikely.

Partition coefficient: n- : log Pow: -4.3 (77 °F / 25 °C)

octanol/water pH: 4.5

**Mobility in soil**No data available

### Other adverse effects

**Product:** 

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I



# cobas SARS-CoV-2 & Influenza A/B

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Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).

Additional ecological

information

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Do not contaminate ponds, waterways or ditches with

chemical or used container.

Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.

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

### **SECTION 14. TRANSPORT INFORMATION**

# **International Regulations**

### **UNRTDG**

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

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

Not applicable

# **Domestic regulation**

#### **49 CFR**

Not regulated as a dangerous good

# Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

# **SECTION 15. REGULATORY INFORMATION**

### **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

# SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.



# cobas SARS-CoV-2 & Influenza A/B

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### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitization

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI

Intermediate or Final VOC's (40 CFR 60.489):

1,2,3-Propanetriol 56-81-5 >= 30 - < 50 %

#### **Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

### **US State Regulations**

### Massachusetts Right To Know

1,2,3-Propanetriol 56-81-5

Pennsylvania Right To Know

Water 7732-18-5 1,2,3-Propanetriol 56-81-5

### **Maine Chemicals of High Concern**

Product does not contain any listed chemicals

### **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

### **Washington Chemicals of High Concern**

Product does not contain any listed chemicals

### **California Permissible Exposure Limits for Chemical Contaminants**

1,2,3-Propanetriol 56-81-5

#### The ingredients 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.



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Proteinase K

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

ENCS : Not in compliance with the inventory

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

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

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

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

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

TECI: Not in compliance with the inventory

#### **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

### **SECTION 16. OTHER INFORMATION**

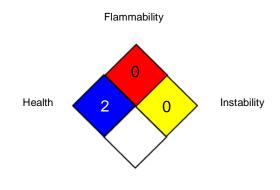
### **Further information**



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#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated

values)

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1

Limits for Air Contaminants

OSHA P0 / TWA : 8-hour time weighted average OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL -Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS -Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration: NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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



# cobas SARS-CoV-2 & Influenza A/B

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- Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 08-20-2025

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.

US / Z8 / 2404



# cobas SARS-CoV-2 & Influenza A/B

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#### **SECTION 1. IDENTIFICATION**

Product name : LIAT MAGNETIC PARTICLES

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

Indianapolis, IN 46250

USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals

Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

### **GHS** label elements

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

#### Other hazards

None known.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

### Components

No hazardous ingredients

### **SECTION 4. FIRST AID MEASURES**

General advice : Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.



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In case of skin contact : Wash off with soap and water.

In case of eye contact : 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.

Most important symptoms

and effects, both acute and

delayed

None known.

Notes to physician : Treat symptomatically.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

No hazardous combustion products are known

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures Refer to protective measures listed in sections 7 and 8.

Environmental precautions : No special environmental precautions required.



# cobas SARS-CoV-2 & Influenza A/B

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Methods and materials for containment and cleaning up

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

#### **SECTION 7. HANDLING AND STORAGE**

Advice on protection against :

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling : For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Conditions for safe storage : Electrical installations / working materials must comply with

the technological safety standards.

Further information on storage conditions

See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on

storage stability

No decomposition if stored and applied as directed.

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

### Personal protective equipment

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 : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit



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Hygiene measures : General industrial hygiene practice.

### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : dark brown

Odor : none

Odor Threshold : No data available

pH : 7.0 (68 °F / 20 °C)

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

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

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.024 g/cm3 (68 - 77 °F / 20 - 25 °C, 990 - 1,030 hPa)

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n- : No data available



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octanol/water

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle Size Distribution : Not applicable

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : No data available

Not applicable

Hazardous decomposition

products

No decomposition if stored and applied as directed.

No hazardous decomposition products are known.

### **SECTION 11. TOXICOLOGICAL INFORMATION**

### **Acute toxicity**

Not classified due to lack of data.

#### Skin corrosion/irritation

Not classified due to lack of data.

#### Serious eye damage/eye irritation

Not classified due to lack of data.



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### Respiratory or skin sensitization

#### Skin sensitization

Not classified due to lack of data.

# Respiratory sensitization

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.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

### 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.

# **Further information**

**Product:** 

Remarks : No data available

#### **SECTION 12. ECOLOGICAL INFORMATION**

# **Ecotoxicity**

No data available

#### Persistence and degradability

No data available

#### Bioaccumulative potential

No data available

# Mobility in soil

No data available

# Other adverse effects

**Product:** 



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Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).

Additional ecological

information

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : 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.

#### **SECTION 14. TRANSPORT INFORMATION**

### **International Regulations**

### **UNRTDG**

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

### **IMDG-Code**

Not regulated as a dangerous good

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

Not applicable

# **Domestic regulation**

#### **49 CFR**

Not regulated as a dangerous good

### Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

### **SECTION 15. REGULATORY INFORMATION**

# **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

# SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.



# cobas SARS-CoV-2 & Influenza A/B

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### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

#### **Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

# **US State Regulations**

# **Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

### Pennsylvania Right To Know

Water 7732-18-5

### **Maine Chemicals of High Concern**

Product does not contain any listed chemicals

#### Vermont Chemicals of High Concern

Product does not contain any listed chemicals

### **Washington Chemicals of High Concern**

Product does not contain any listed chemicals

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Magnetic glass particles (MGP)

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



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ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

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

TECI: Not in compliance with the inventory

#### **TSCA list**

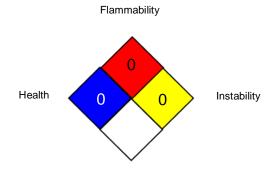
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

### **SECTION 16. OTHER INFORMATION**

# **Further information**

### NFPA 704:



Special hazard

### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -



### cobas SARS-CoV-2 & Influenza A/B

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Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL -Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS -Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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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.

US / Z8 / 2404



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#### **SECTION 1. IDENTIFICATION**

Product name : R7 LYSIS BUFFER

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

Indianapolis, IN 46250

USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals

Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4

Skin corrosion : Category 1C

Serious eye damage : Category 1

**GHS label elements** 

Hazard pictograms





Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.

H314 Causes severe skin burns and 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/ protective clothing/ 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.

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT

induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately

all contaminated clothing. Rinse skin with water/ shower. P304 + P340 + P310 IF INHALED: Remove person to fresh air

and keep comfortable for breathing. Immediately call a POISON

CENTER/ doctor.

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

P363 Wash contaminated clothing before reuse.

#### Storage:

P405 Store locked up.

### Disposal:

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

### Other hazards

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Thiocyanic acid, compd. with	593-84-0	>= 30 - < 50
guanidine (1:1)		
Poly(oxy-1,2-ethanediyl), .alpha	9002-92-0	>= 5 - < 10
dodecylomegahydroxy-		
Citric acid monohydrate	5949-29-1	>= 1 - < 5

Actual concentration is withheld as a trade secret

### **SECTION 4. FIRST AID MEASURES**

General advice : Move out of dangerous area.

Consult a physician.

Show this material safety data sheet to the doctor in

attendance.

Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

In case of skin contact : Immediate medical treatment is necessary as untreated



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wounds from corrosion of the skin heal slowly and with

difficulty.

If on skin, rinse well with water. If on clothes, remove clothes.

In case of eye contact : Small amounts splashed into eyes can cause irreversible

tissue damage and blindness.

In the case of contact with eyes, rinse immediately with plenty

of water and seek medical advice.

Continue rinsing eyes during transport to hospital.

Remove contact lenses. Protect unharmed eye.

Keep eye wide open while rinsing.

If eye irritation persists, consult a specialist.

If swallowed : 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.

Most important symptoms and effects, both acute and

delayed

: Harmful if swallowed.

Causes serious eye damage.

Causes severe burns.

Notes to physician : Treat symptomatically.

### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

Do not allow run-off from fire fighting to enter drains or water

courses.

Hazardous combustion

products

: Ammonia Carbon oxides

Hydrogen cyanide (hydrocyanic acid)

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.



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Special protective equipment :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures

Use personal protective equipment.

Refer to protective measures listed in sections 7 and 8.

Prevent product from entering drains. Environmental precautions

Prevent further leakage or spillage if safe to do so.

If the product contaminates rivers and lakes or drains inform

respective authorities.

Methods and materials for containment and cleaning up Neutralize with chalk, alkali solution or ammonia.

Soak up with inert absorbent material (e.g. sand, silica gel,

acid binder, universal binder, sawdust).

Keep in suitable, closed containers for disposal.

#### **SECTION 7. HANDLING AND STORAGE**

fire and explosion

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

Advice on safe handling Do not breathe vapors/dust.

Avoid contact with skin and eyes. For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

To avoid spills during handling keep bottle on a metal tray. Dispose of rinse water in accordance with local and national

regulations.

Conditions for safe storage

Keep container tightly closed in a dry and well-ventilated

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

Do not store near acids. Materials to avoid

Further information on

storage stability

No decomposition if stored and applied as directed.



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#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Thiocyanic acid, compd. with guanidine (1:1)	593-84-0	IOEL	100 microgram per cubic meter	Category 1 (Roche Group Directive K1, Annex 3): OEL = 100 µg/m3

**Engineering measures** : No data available

Personal protective equipment

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Wear face-shield and protective suit for abnormal processing

problems.

Skin and body protection : Impervious clothing

Choose body protection according to the amount and

concentration of the dangerous substance at the work place.

Hygiene measures : When using do not eat or drink.

When using do not smoke.

Wash hands before breaks and at the end of workday.

# **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 2.4



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Concentration: 100 %

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : No data available

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

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.085 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : No data available

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

Particle characteristics



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Particle Size Distribution : Not applicable

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

No decomposition if stored and applied as directed.

Conditions to avoid : No data available

Incompatible materials : Strong acids

Strong oxidizing agents

Cyanides

sodium hypochlorite

Not applicable

Hazardous decomposition

products

No decomposition if stored and applied as directed.

In case of fire hazardous decomposition products may be

produced such as: Carbon oxides

Nitrogen oxides (NOx)

Sulfur oxides

No hazardous decomposition products are known.

### **SECTION 11. TOXICOLOGICAL INFORMATION**

### **Acute toxicity**

Harmful if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 1,395 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 25.86 mg/l

Exposure time: 4 h
Test atmosphere: vapor
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: 2,504 mg/kg

Method: Calculation method

### **Components:**

Thiocyanic acid, compd. with guanidine (1:1):

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

Method: OECD Test Guideline 401



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Symptoms: Vomiting

GLP: yes

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract., The

component/mixture is moderately toxic after short term

inhalation.

Acute dermal toxicity : Assessment: The component/mixture is moderately toxic after

single contact with skin.

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Acute oral toxicity : LD50 Oral (Rat): 8,600 mg/kg

Citric acid monohydrate:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

GLP: yes

Skin corrosion/irritation

Causes severe burns.

**Product:** 

Remarks : Extremely corrosive and destructive to tissue.

Components:

Thiocyanic acid, compd. with guanidine (1:1):

Species : Rabbit Exposure time : 4 h

Method : OECD Test Guideline 404

Result : Corrosive after 1 to 4 hours of exposure

GLP : yes

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Species : Rabbit

Result : No skin irritation



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# Citric acid monohydrate:

Species : Rabbit Exposure time : 4 h

Method : OECD Test Guideline 404

Result : No skin irritation

# Serious eye damage/eye irritation

Causes serious eye damage.

**Product:** 

Remarks : May cause irreversible eye damage.

# **Components:**

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

Result : Mild eye irritation

### Citric acid monohydrate:

Result : Irritating to eyes.

Method : OECD Test Guideline 405

### Respiratory or skin sensitization

# Skin sensitization

Not classified due to lack of data.

### Respiratory sensitization

Not classified due to lack of data.

# **Components:**

### Citric acid monohydrate:

Assessment : Did not cause sensitization on laboratory animals.

### Germ cell mutagenicity

Not classified due to lack of data.

### **Components:**

# Thiocyanic acid, compd. with guanidine (1:1):

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



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Test Type: Chromosome aberration test in vitro

Test system: Human lymphocytes

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 473

Result: negative

GLP: no

Test Type: gene mutation test Test system: mouse lymphoma cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative GLP: yes

### Citric acid monohydrate:

Genotoxicity in vitro : Test Type: reverse mutation assay

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

Test Type: Microbial mutagenesis assay (Ames test)

Test system: Salmonella typhimurium Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Test Type: Micronucleus test Test system: Human lymphocytes Method: OECD Test Guideline 487

Result: positive

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro

Species: Rat

Cell type: Bone marrow

Method: OECD Test Guideline 475

Result: negative

Test Type: dominant lethal test

Species: Rat

Application Route: Oral

Method: Regulation (EC) No. 440/2008, Annex, B.22

Result: negative

### Carcinogenicity

Not classified due to lack of data.

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



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**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Not classified due to lack of data.

### Components:

### Thiocyanic acid, compd. with guanidine (1:1):

Effects on fertility : Species: Rat, female

Application Route: Oral

Dose: 25 GLP: no

Remarks: No significant adverse effects were reported

Based on data from similar materials

Effects on fetal development : Species: Rat, female

Application Route: Oral

Dose: 50, 150, 350 mg/kg bw/day

General Toxicity Maternal: NOAEL: 150 mg/kg bw/day Embryo-fetal toxicity.: NOAEL: 350 mg/kg body weight

Method: OECD Test Guideline 414

GLP: yes

# STOT-single exposure

Not classified due to lack of data.

### **Components:**

# Citric acid monohydrate:

Target Organs : Respiratory system

Assessment : May cause respiratory irritation.

### STOT-repeated exposure

Not classified due to lack of data.

### Repeated dose toxicity

# **Components:**

### Thiocyanic acid, compd. with guanidine (1:1):

Species : Rat, male and female

NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 90 d
Number of exposures : daily

Dose : 25, 100, 300 mg/kg bw/day Method : OECD Test Guideline 408

GLP : yes



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Citric acid monohydrate:

Species : Rat

NOAEL : 1,200 mg/kg

Application Route : Oral

**Aspiration toxicity** 

Not classified due to lack of data.

**Further information** 

**Product:** 

Remarks : No data available

#### **SECTION 12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

#### **Components:**

Thiocyanic acid, compd. with guanidine (1:1):

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89.1 mg/l

End point: mortality Exposure time: 96 h Test Type: static test Analytical monitoring: no

Method: OECD Test Guideline 203

GLP: no

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia): 42.4 mg/l End point: Immobilization

Exposure time: 48 h Test Type: static test Analytical monitoring: no

Method: OECD Test Guideline 202

GLP: no

Toxicity to algae/aquatic

plants

EC50 (Desmodesmus subspicatus (green algae)): 130 mg/l

End point: Growth rate Exposure time: 72 h Test Type: static test

GLP: No information available.

Toxicity to microorganisms : EC50 (activated sludge): > 185 mg/l

Exposure time: 28 d Test Type: static test

Method: OECD Test Guideline 302B

GLP: yes

**Ecotoxicology Assessment** 

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



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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-:

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 6.46 mg/l

Exposure time: 48 h

M-Factor (Acute aquatic

toxicity)

**Ecotoxicology Assessment** 

Acute aquatic toxicity Harmful to aquatic life.

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

Citric acid monohydrate:

Toxicity to fish LC50 (Leuciscus idus (Golden orfe)): 440 mg/l

> Exposure time: 48 h Test Type: static test

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 120 mg/l

Exposure time: 72 h

The value is given in analogy to the following substances:

Citric acid

Toxicity to algae/aquatic

plants

(Scenedesmus quadricauda (Green algae)): 640 mg/l

Exposure time: 7 h

Remarks: No toxicity at the limit of solubility.

**Ecotoxicology Assessment** 

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

Chronic aquatic toxicity This product has no known ecotoxicological effects.

Toxicity Data on Soil Not expected to adsorb on soil.

Other organisms relevant to

the environment

No data available



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### Persistence and degradability

### Components:

# Thiocyanic acid, compd. with guanidine (1:1):

Biodegradability : aerobic

Inoculum: activated sludge, non-adapted

Concentration: 343 mg/l

Result: Inherently biodegradable.

Biodegradation: 46 % Exposure time: 28 d

Method: OECD Test Guideline 302B

GLP: no

Citric acid monohydrate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

### **Bioaccumulative potential**

### **Components:**

### Thiocyanic acid, compd. with guanidine (1:1):

Partition coefficient: n- : log Pow: -1.11 (77 °F / 25 °C)

octanol/water pH: > 5.1

Method: Regulation (EC) No. 440/2008, Annex, A.8

GLP: no

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

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 220

Exposure time: 72 h

Partition coefficient: n-

octanol/water

: Remarks: No data available

### Citric acid monohydrate:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water,

accumulation in organisms is not expected.

Partition coefficient: n-

octanol/water

log Pow: -1.72 (68 °F / 20 °C) Method: OECD Test Guideline 117

Remarks: anhydrous substance

The value is given in analogy to the following substances:

Citric acid

### Mobility in soil

No data available



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#### Other adverse effects

**Product:** 

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).

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.

# **Components:**

Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-:

Additional ecological

information

: No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

### **Disposal methods**

Waste from residues : The product should not be allowed to enter drains, water

courses or the soil.

Do not contaminate ponds, waterways or ditches with

chemical or used container.

Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.

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

### **SECTION 14. TRANSPORT INFORMATION**

# International Regulations

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

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

Not applicable

### **Domestic regulation**

#### **49 CFR**

Not regulated as a dangerous good



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Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

#### **SECTION 15. REGULATORY INFORMATION**

### **CERCLA Reportable Quantity**

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

# SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Acute toxicity (any route of exposure)

Skin corrosion or irritation

Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

#### **Clean Water Act**

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Phosphoric acid, sodium 7558-79-4 >= 0.1 - < 1 %

salt (1:2)

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Phosphoric acid, sodium 7558-79-4 >= 0.1 - < 1 %

salt (1:2)

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

### **US State Regulations**

#### Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

### Pennsylvania Right To Know

Water 7732-18-5



# cobas SARS-CoV-2 & Influenza A/B

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Thiocyanic acid, compd. with guanidine (1:1) 593-84-0
Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxyCitric acid monohydrate 5949-29-1
Phosphoric acid, sodium salt (1:2) 7558-79-4

### **Maine Chemicals of High Concern**

Product does not contain any listed chemicals

#### **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

### **Washington Chemicals of High Concern**

Product does not contain any listed chemicals

### The ingredients 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 : Not in compliance with the inventory

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

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

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

TSCA : All substances listed as active on the TSCA inventory

TECI: Not in compliance with the inventory

#### **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

#### **SECTION 16. OTHER INFORMATION**

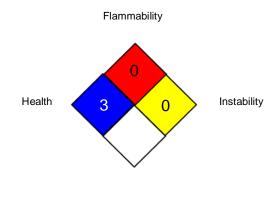
### **Further information**



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#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL -Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS -Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand



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Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 08-20-2025

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**

Product name : Wash Buffer

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

Indianapolis, IN 46250

USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals

Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

## **GHS** label elements

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

#### Other hazards

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Glycine	56-40-6	>= 1 - < 5

Actual concentration is withheld as a trade secret

## **SECTION 4. FIRST AID MEASURES**

General advice : Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical



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advice.

If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.

In case of eye contact : 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.

Most important symptoms and effects, both acute and

delayed

None known.

Notes to physician : Treat symptomatically.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

Carbon oxides

Nitrogen oxides (NOx)

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures Refer to protective measures listed in sections 7 and 8.



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Environmental precautions : If the product contaminates rivers and lakes or drains inform

respective authorities.

Methods and materials for

containment and cleaning up

Neutralize with chalk, alkali solution or ammonia. Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

**SECTION 7. HANDLING AND STORAGE** 

Advice on protection against :

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling : For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Conditions for safe storage : Electrical installations / working materials must comply with

the technological safety standards.

Further information on

storage conditions

See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Do not store near acids.

Further information on

storage stability

No decomposition if stored and applied as directed.

## **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

## Personal protective equipment

Hand protection

In case of full contact:

Material : Nitrile rubber
Break through time : 480 min
Glove thickness : 0.11 mm

In case of contact through splashing:

Material : Nitrile rubber
Break through time : 480 min
Glove thickness : 0.11 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.



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Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : General industrial hygiene practice.

## **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 4.0

Concentration: 100 %

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.006 g/cm3



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Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle Size Distribution : Not applicable

## **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : No data available

Not applicable

Hazardous decomposition

products

: No data available

No hazardous decomposition products are known.

## **SECTION 11. TOXICOLOGICAL INFORMATION**

## **Acute toxicity**

Not classified due to lack of data.

### **Components:**

Glycine:



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Acute oral toxicity : LD50 Oral (Rat): 7,930 mg/kg

#### Skin corrosion/irritation

Not classified due to lack of data.

#### **Components:**

Glycine:

Species : Rabbit Exposure time : 4 h

Method : OECD Test Guideline 404

Result : negative GLP : yes

## Serious eye damage/eye irritation

Not classified due to lack of data.

## **Components:**

Glycine:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

GLP : yes

#### Respiratory or skin sensitization

#### Skin sensitization

Not classified due to lack of data.

#### Respiratory sensitization

Not classified due to lack of data.

## Germ cell mutagenicity

Not classified due to lack of data.

## **Components:**

Glycine:

Genotoxicity in vitro : Test Type: Ames test

Result: negative

Test Type: In vitro mammalian cell gene mutation test Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative

GLP: yes

## Carcinogenicity

Not classified due to lack of data.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is



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on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified due to lack of data.

STOT-single exposure

Not classified due to lack of data.

**Components:** 

Glycine:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

STOT-repeated exposure

Not classified due to lack of data.

**Components:** 

Glycine:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

**Aspiration toxicity** 

Not classified due to lack of data.

**Further information** 

**Product:** 

Remarks : No data available

## **SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity** 

**Components:** 

Glycine:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 1,000 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 220 mg/l

Exposure time: 48 h Test Type: semi-static test

Method: OECD Test Guideline 202

GLP: yes

Toxicity to algae/aquatic

plants

NOEC (Pseudokirchneriella subcapitata (green algae)): >

1,000 mg/l



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Exposure time: 72 h

Method: OECD Test Guideline 201

GLP: no

**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

Persistence and degradability

**Components:** 

Glycine:

Biodegradability : see user defined free text

Result: Readily biodegradable. Biodegradation: 76 - 82 %

Exposure time: 14 d

Method: OECD Test Guideline 301C

**Bioaccumulative potential** 

**Components:** 

Glycine:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-

octanol/water

log Pow: -3.21

Mobility in soil

No data available

Other adverse effects

**Product:** 

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).

Additional ecological

information

No data available



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#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : 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.

#### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

**UNRTDG** 

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

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

Not applicable

**Domestic regulation** 

**49 CFR** 

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

#### **SECTION 15. REGULATORY INFORMATION**

## **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.



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#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

Glycine 56-40-6 >= 1 - < 5 %

#### **Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

#### **US State Regulations**

## Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

## Pennsylvania Right To Know

Water 7732-18-5

#### **Maine Chemicals of High Concern**

Product does not contain any listed chemicals

#### **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

#### Washington Chemicals of High Concern

Product does not contain any listed chemicals

## The ingredients 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.

**Glycols** 

Modified alkyl carboxylate

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



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PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

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

TECI: Not in compliance with the inventory

#### **TSCA list**

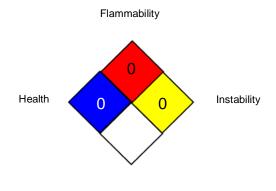
No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

#### **SECTION 16. OTHER INFORMATION**

#### **Further information**

#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous



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Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified: NFPA - National Fire Protection Association: NO(A)EC - No Observed (Adverse) Effect Concentration: NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 08-20-2025

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#### **SECTION 1. IDENTIFICATION**

Product name : Elution Buffer

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

Indianapolis, IN 46250

USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada) 1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals

Refer to product literature for further details.

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

## **GHS** label elements

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

#### Other hazards

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

No hazardous ingredients

#### **SECTION 4. FIRST AID MEASURES**

General advice : Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical

advice.

If symptoms persist, call a physician.

Elution Buffer 122



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In case of skin contact : Wash off with soap and water.

In case of eye contact : 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.

Most important symptoms

and effects, both acute and

delayed

None known.

Notes to physician : Treat symptomatically.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion

products

No hazardous combustion products are known

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

## **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures Refer to protective measures listed in sections 7 and 8.

Environmental precautions : If the product contaminates rivers and lakes or drains inform

Elution Buffer 123



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respective authorities.

Methods and materials for

containment and cleaning up

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

#### **SECTION 7. HANDLING AND STORAGE**

fire and explosion

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

Advice on safe handling For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Conditions for safe storage Electrical installations / working materials must comply with

the technological safety standards.

Further information on

storage conditions

See label, package insert or internal guidelines

Materials to avoid No materials to be especially mentioned.

Further information on

storage stability

No decomposition if stored and applied as directed.

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

## Personal protective equipment

Hand protection

In case of full contact:

Material : Nitrile rubber Break through time : 480 min Glove thickness : 0.11 mm

In case of contact through splashing:

Material Nitrile rubber Break through time 480 min Glove thickness 0.11 mm

Remarks Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection Safety glasses

Skin and body protection Protective suit



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Hygiene measures : General industrial hygiene practice.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.0125 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available



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Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics

Particle Size Distribution : Not applicable

#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid : No data available

Incompatible materials : No data available

Not applicable

Hazardous decomposition

products

No data available

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

#### **Acute toxicity**

Not classified due to lack of data.

## Skin corrosion/irritation

Not classified due to lack of data.

## Serious eye damage/eye irritation

Not classified due to lack of data.



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## Respiratory or skin sensitization

#### Skin sensitization

Not classified due to lack of data.

#### Respiratory sensitization

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.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

#### 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.

## **Further information**

**Product:** 

Remarks : No data available

#### **SECTION 12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

No data available

#### Persistence and degradability

No data available

#### Bioaccumulative potential

No data available

## Mobility in soil

No data available

#### Other adverse effects

**Product:** 



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Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I

Substances

Remarks: This product neither contains, nor was

manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +

B).

Additional ecological

information

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : 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.

#### **SECTION 14. TRANSPORT INFORMATION**

#### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

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

Not applicable

## **Domestic regulation**

#### **49 CFR**

Not regulated as a dangerous good

## Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

## **SECTION 15. REGULATORY INFORMATION**

## **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

## SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.



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## SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

#### **Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

## **US State Regulations**

## **Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

## Pennsylvania Right To Know

Water 7732-18-5 .alpha.-D-Glucopyranoside, .alpha.-D-glucopyranosyl 99-20-7

## **Maine Chemicals of High Concern**

Product does not contain any listed chemicals

## **Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

#### **Washington Chemicals of High Concern**

Product does not contain any listed chemicals

#### The ingredients 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.

Glycols



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Modified alkyl carboxylate

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

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

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

TECI: Not in compliance with the inventory

#### **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

#### **SECTION 16. OTHER INFORMATION**

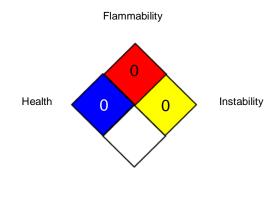
## **Further information**



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#### NFPA 704:



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL -Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS -Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand



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Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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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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