SAFETY DATA SHEET

cobas Cdiff

Version	Revision Date:	Date of last issue: 08-29-2024
1.4	08-29-2024	Date of first issue: 10-26-2020

Cover letter for product:

Trade name : cobas Cdiff
Product code : 07454945190

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

- METAL 3
- MMX-2
- MMX-1
- EB
- WASH
- Lysis
- LMP
- PROK
- IC

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

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

SECTION 1. IDENTIFICATION

Product name : METAL 3

Manufacturer or supplier's details

Company name of supplier	:	Roche Diagnostics Deutschland GmbH
Address	:	116 Sandhoferstrasse Mannheim, 68305 Deutschland
Telephone	:	+496217590
Telefax	:	+496217592890
E-mail address	:	info.dia-sds@roche.com
Emergency telephone Im Notfall:	:	Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203
Giftnotruf:	:	Mainz +49(0)6131-19240

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	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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	:	Local authorities should be advised if significant spillages cannot be contained.

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

Respiratory protection	:	No personal respiratory protective equipment normally required.
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

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	colorless
Odor	:	characteristic
Odor Threshold	:	No data available
pH	:	6.3
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
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-	:	No data available

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.

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
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.

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.

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:

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).

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. 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
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).
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:

Acetic acid	64-19-7	>= 0 - < 0.1 %

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

Acetic acid	64-19-7	>= 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

Sodium azide (Na(N3))	26628-22-8

Pennsylvania Right To Know

Water	7732-18-5
Acetic acid, manganese(2+) salt, tetrahydrate	6156-78-1
Sodium azide (Na(N3))	26628-22-8
Acetic acid	64-19-7

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	:	On the inventory, or in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Acetic acid, manganese(2+) salt, tetrahydrate Magnesium di(acetate)Tetrahydrate
NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	Not in compliance with the inventory

ISHL	:	Not in compliance with the inventory
KECI	:	On the inventory, or in compliance with the inventory
PICCS	:	On the inventory, or in compliance with the inventory
IECSC	:	On the inventory, or in compliance with the inventory
TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

TSCA list

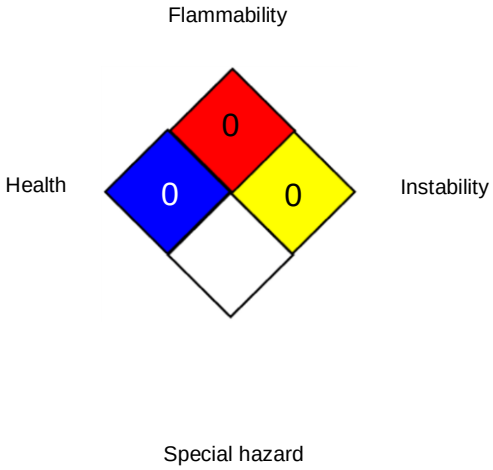
No substances are subject to a Significant New Use Rule.

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

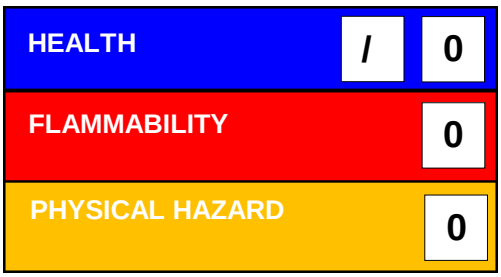
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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 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 : 08-29-2024

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 / 2304

SECTION 1. IDENTIFICATION

Product name : MMX-2

Manufacturer or supplier's details

Company name of supplier	:	Roche Diagnostics Deutschland GmbH
Address	:	116 Sandhoferstrasse Mannheim, 68305 Deutschland
Telephone	:	+496217590
Telefax	:	+496217592890
E-mail address	:	info.dia-sds@roche.com
Emergency telephone Im Notfall:	:	Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203
Giftnotruf:	:	Mainz +49(0)6131-19240

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
DNA-dependent DNA polymerase	9012-90-2	< 0.1
Uracil DNA Glycosylase	59088-21-0	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice	:	Do not leave the victim unattended.
If inhaled	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during fire fighting	:	No information available.
Hazardous combustion products	:	Oxides of phosphorus 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.

Environmental precautions	:	Local authorities should be advised if significant spillages cannot be contained.
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
DNA-dependent DNA polymerase	9012-90-2	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)
Uracil DNA Glycosylase	59088-21-0	IOEL	0.00006 mg/m3	Roche Industrial

				Hygiene Committee (RIHC)

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	8.28
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	:	No data available
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
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.

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
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 Oxides of phosphorus

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.

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
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.

Components:

DNA-dependent DNA polymerase:

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

Uracil DNA Glycosylase:

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:

DNA-dependent DNA polymerase:

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

Uracil DNA Glycosylase:

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

Uracil DNA Glycosylase:

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 GLP: no
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Daphnia magna (Water flea)): 1,955 mg/l End point: mortality Exposure time: 48 h Test Type: static test Analytical monitoring: no

GLP: no

Toxicity to algae/aquatic plants : (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l
End point: Growth rate
Exposure time: 8 d
Test Type: static test
GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10,000 mg/l
End point: Growth rate
Exposure time: 16 h
Test Type: static test
GLP: No information available.

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

DNA-dependent DNA polymerase:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Uracil DNA Glycosylase:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

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-octanol/water : log Pow: -1.75 (77 °F / 25 °C)
pH: 7.4
Method: OECD Test Guideline 107
GLP: no

DNA-dependent DNA polymerase:

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

Uracil DNA Glycosylase:

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).

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.
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

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

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
Sodium azide (Na(N3))	26628-22-8

Pennsylvania Right To Know

Water	7732-18-5
Uridine 5'-(tetrahydrogen triphosphate), 2'-deoxy-	1173-82-6
1,2,3-Propanetriol	56-81-5
Sodium azide (Na(N3))	26628-22-8

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. Uridine 5'-(tetrahydrogen triphosphate), 2'-deoxy- Adenosine 5'-(tetrahydrogen triphosphate), 2'-deoxy- Guanosine 5'-(tetrahydrogen triphosphate), 2'-deoxy- Cytidine 5'-(tetrahydrogen triphosphate), 2'-deoxy- Primer / Oligonucleotide / Probe Uracil DNA Glycosylase DNA-dependent 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

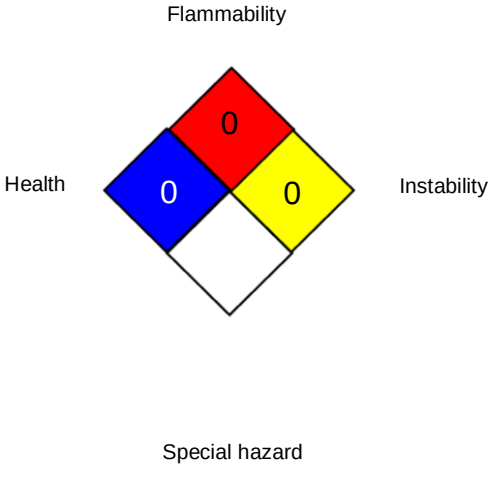
No substances are subject to a Significant New Use Rule.

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

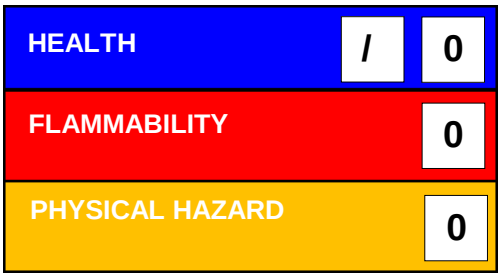
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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 - 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 : 08-29-2024

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 / 2304

SECTION 1. IDENTIFICATION

Product name : MMX-1

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse
Mannheim, 68305
Deutschland

Telephone : +496217590
Telefax : +496217592890
E-mail address : info.dia-sds@roche.com
Emergency telephone
Im Notfall: : Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203

Giftnotruf: : Mainz +49(0)6131-19240

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)
Methane, 1,1'-sulfinylbis-	67-68-5	>= 10 - < 20
Acetic acid, potassium salt (1:1)	127-08-2	>= 5 - < 10

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice	:	Do not leave the victim unattended.
If inhaled	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during fire fighting	:	No information available.
Hazardous combustion products	:	Carbon oxides Sulfur 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.
Methods and materials for	:	Wipe up with absorbent material (e.g. cloth, fleece).

containment and cleaning up | 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
Methane, 1,1'-sulfinylbis-	67-68-5	TWA	250 ppm	US WEEL

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	No data available
Odor	:	characteristic
Odor Threshold	:	No data available
pH	:	8.75
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	:	No data available
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
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.

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
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 Sulfur oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:

Methane, 1,1'-sulfinylbis-:

Acute oral toxicity	:	LD50 (Rat, male and female): 28,300 mg/kg

Method: OECD Test Guideline 401
GLP: no

Acute inhalation toxicity : LC0 (Rat, male and female): > 5.33 mg/l
Exposure time: 4 h
Test atmosphere: vapor
Method: OECD Test Guideline 403
GLP: yes

Acute dermal toxicity : LD50 Dermal (Rat, male and female): 40,000 mg/kg
GLP: no

Acetic acid, potassium salt (1:1):

Acute oral toxicity : LD50 Oral (Rat): 3,250 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

LC50 (Rat): > 5.6 mg/l
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: No mortality observed at this dose.

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

Skin corrosion/irritation

Not classified due to lack of data.

Components:

Methane, 1,1'-sulfinylbis-:

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

Acetic acid, potassium salt (1:1):

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

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:

Methane, 1,1'-sulfinylbis-:

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

Acetic acid, potassium salt (1:1):

Species	:	Rabbit
Result	:	No eye irritation
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:

Methane, 1,1'-sulfinylbis-:

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

Germ cell mutagenicity

Not classified due to lack of data.

Components:

Methane, 1,1'-sulfinylbis-:

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 471 Result: negative GLP: No information available. Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells Metabolic activation: with and without metabolic activation Method: OECD Test Guideline 473 Result: negative GLP: No information available. Test Type: sister chromatid exchange assay

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

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

Carcinogenicity

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:

Methane, 1,1'-sulfinylbis-:

Effects on fertility : Species: Rat, male and female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Fertility: NOAEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 421
GLP: yes

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: 200, 1000, 5000 milligram per kilogram
Duration of Single Treatment: 10 d
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

Components:

Methane, 1,1'-sulfinylbis-:

Species	:	Monkey, male and female
NOAEL	:	2970 mg/kg
NOAEL	:	2,970 mg/kg
Application Route	:	Oral
Exposure time	:	87 Weeks
Dose	:	990, 2970, 8910 mg/kg
Method	:	OECD Test Guideline 452
GLP	:	no

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

Species	:	Monkey, male and female
NOAEL	:	> 8910 mg/kg
NOAEL	:	> 8,910 mg/kg
Application Route	:	Dermal
Exposure time	:	18 Months
Dose	:	990, 2970, 8910 mg/kg bw/da
Method	:	OECD Test Guideline 452
GLP	:	no

Repeated dose toxicity - Assessment	:	Mild eye irritation, Mild skin irritation

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Methane, 1,1'-sulfinylbis-:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 25,000 mg/l End point: mortality Exposure time: 96 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 203 GLP: yes
Toxicity to daphnia and other	:	EC50 (Daphnia magna (Water flea)): 24,600 mg/l

aquatic invertebrates		Exposure time: 48 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 202 GLP: No information available.
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 17,000 mg/l End point: Growth rate Exposure time: 72 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 201 GLP: yes
Toxicity to microorganisms	:	EC50 (activated sludge): 10 - 100 mg/l Exposure time: 0.5 h Analytical monitoring: no Method: ISO 8192 GLP: No information available.

Ecotoxicology Assessment

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

Acetic acid, potassium salt (1:1):

Toxicity to fish	:	LC50 (Brachydanio rerio (zebrafish)): 496.35 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 459.5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202

Ecotoxicology Assessment

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

Persistence and degradability

Components:

Methane, 1,1'-sulfinylbis-:

Biodegradability	:	aerobic Inoculum: activated sludge Concentration: 2 mg/l Result: Not readily biodegradable.

Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

Acetic acid, potassium salt (1:1):

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential

Components:

Methane, 1,1'-sulfinylbis-:

Partition coefficient: n-octanol/water : log Pow: -1.35 (68 °F / 20 °C)
pH: 7
GLP: No information available.

Acetic acid, potassium salt (1:1):

Bioaccumulation : Bioconcentration factor (BCF): 3.16
Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

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).

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.
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
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):

Methane, 1,1'-sulfinylbis-	67-68-5	>= 10 - < 20 %

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-ethanediylbis[N-(carboxymethyl)-	60-00-4	>= 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-ethanediylbis[N-(carboxymethyl)-	60-00-4	>= 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

Sodium azide (Na(N3))	26628-22-8

Pennsylvania Right To Know

Water	7732-18-5
Methane, 1,1'-sulfinylbis-	67-68-5
Acetic acid, potassium salt (1:1)	127-08-2
Glycine, N-[2-hydroxy-1,1-bis(hydroxymethyl)ethyl]-	5704-04-1
Sodium azide (Na(N3))	26628-22-8
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. 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

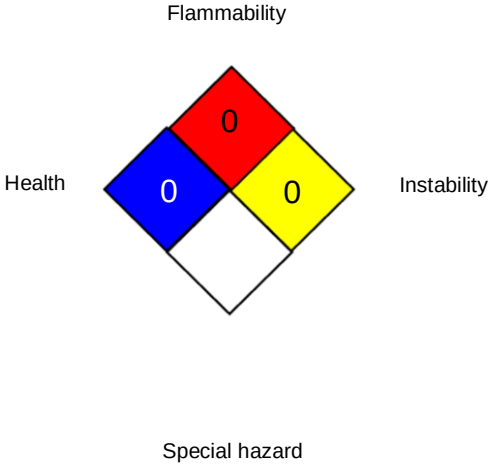
No substances are subject to a Significant New Use Rule.

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

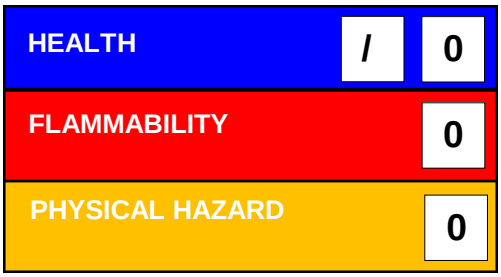
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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-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 : 08-29-2024

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 / 2304

SECTION 1. IDENTIFICATION

Product name : EB

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse
Mannheim, 68305
Deutschland

Telephone : +496217590
Telefax : +496217592890
E-mail address : info.dia-sds@roche.com
Emergency telephone
Im Notfall: : Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203

Giftnotruf: : Mainz +49(0)6131-19240

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)
Albumins, human	70024-90-7	>= 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	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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	:	Local authorities should be advised if significant spillages

cannot be contained.

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

Respiratory protection	:	No personal respiratory protective equipment normally required.
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
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	8.7
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	:	No data available
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
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.

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
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.

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.

Components:

Albumins, human:

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.

STOT-repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Albumins, human:

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:

Albumins, human:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

Albumins, human:

Bioaccumulation : Remarks: No data available

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).

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.
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

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).
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

Sodium azide (Na(N3)) 26628-22-8

Pennsylvania Right To Know

Water	7732-18-5
Sodium azide (Na(N3))	26628-22-8

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	:	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	:	All substances listed as active on the TSCA inventory
TECI	:	Not in compliance with the inventory

TSCA list

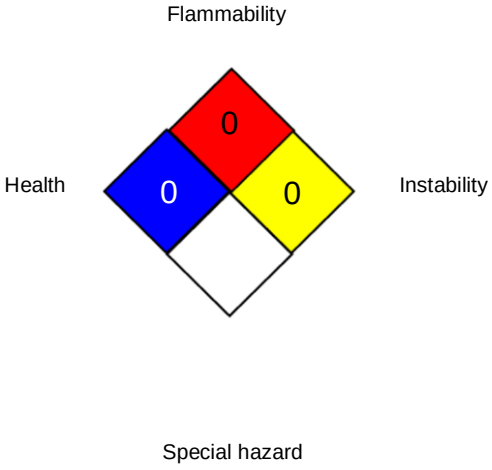
No substances are subject to a Significant New Use Rule.

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

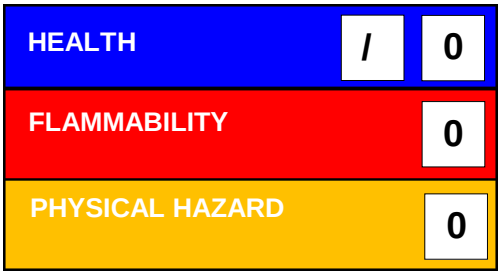
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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

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 : 08-29-2024

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US / Z8 / 2304

SECTION 1. IDENTIFICATION

Product name : WASH

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse
Mannheim, 68305
Deutschland

Telephone : +496217590
Telefax : +496217592890
E-mail address : info.dia-sds@roche.com
Emergency telephone
Im Notfall: : Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203

Giftnotruf: : Mainz +49(0)6131-19240

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)

Skin sensitization : Category 1

GHS label elements

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

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.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
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)
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1)	26172-54-3	>= 0.0015 - < 0.1

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

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

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

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

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.

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

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	:	Use personal protective equipment. 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. Local authorities should be advised if significant spillages cannot be contained.
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.

SECTION 7. HANDLING AND STORAGE

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

Materials to avoid : Keep away from oxidizing agents, strongly alkaline and strongly acid materials in order to avoid exothermic reactions.

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 : 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

Appearance	:	liquid
Color	:	colorless
Odor	:	characteristic
Odor Threshold	:	No data available
pH	:	4.1
Melting point/range	:	No data available
Boiling point/boiling range	:	ca. 212 °F / 100 °C
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	:	1.007 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.

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 oxidizing agents Strong acids and strong bases
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.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Acute oral toxicity	:	LD50 Oral (Rat, female): 175 mg/kg Method: OECD Test Guideline 425
Acute inhalation toxicity	:	LC50 (Rat, male and female): 0.11 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: Corrosive to the respiratory tract. Remarks: Based on data from similar materials The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity	:	LD50 Dermal (Rat, male): 246 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks	:	May cause skin irritation and/or dermatitis.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 431
Result	:	Causes severe burns.

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:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result	:	Risk of serious damage to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks	:	Causes sensitization.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Test Type	:	Local lymph node assay (LLNA)
Method	:	OECD Test Guideline 429
Result	:	The product is a skin sensitizer, sub-category 1A.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type	:	Maximization Test
Species	:	Guinea pig

Method	:	OECD Test Guideline 406
Result	:	positive
Remarks	:	Based on data from similar materials

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Germ cell mutagenicity

Not classified due to lack of data.

Components:

3(2H)-Isothiazolone, 2-methyl-, 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

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Method: OECD Test Guideline 476
Result: negative
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (male and female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay
Species: Rat (male and female)
Application Route: Oral
Method: OECD Test Guideline 486
Result: negative
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

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:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Effects on fetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on fetal development.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species	:	Rat
NOEL	:	94 mg/kg bw/day
Application Route	:	Oral
Exposure time	:	90 d
Method	:	OECD Test Guideline 408
Remarks	:	No significant adverse effects were reported No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species	:	Dog
NOAEL	:	40.9 mg/kg bw/day
Application Route	:	Oral
Exposure time	:	90 d
Method	:	OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203
The value is given in analogy to the following substances: 2-

methyl-2H-isothiazol-3-one

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 2.33 mg/l Exposure time: 48 h Test Type: static test Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l Exposure time: 72 h Test Type: static test Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.0442 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Persistence and degradability

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Biodegradability	:	aerobic Result: Not readily biodegradable. Biodegradation: 0 % Exposure time: 28 d Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Bioaccumulation	:	Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water	:	log Pow: ca. -0.44 (68 °F / 20 °C) Method: OECD Test Guideline 107

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).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

SECTION 14. TRANSPORT INFORMATION

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

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

TSCA list

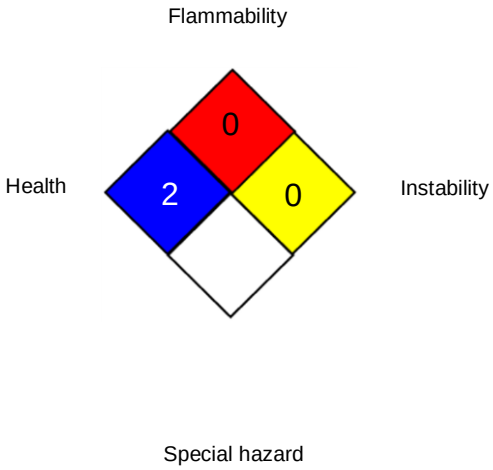
No substances are subject to a Significant New Use Rule.

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

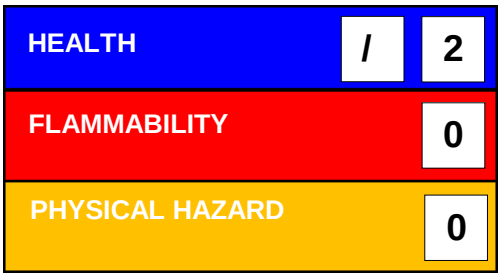
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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 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 : 08-29-2024

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 / 2304

SECTION 1. IDENTIFICATION

Product name : Lysis

Manufacturer or supplier's details

Company name of supplier	:	Roche Diagnostics Deutschland GmbH
Address	:	116 Sandhoferstrasse Mannheim, 68305 Deutschland
Telephone	:	+496217590
Telefax	:	+496217592890
E-mail address	:	info.dia-sds@roche.com
Emergency telephone Im Notfall:	:	Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203
Giftnotruf:	:	Mainz +49(0)6131-19240

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.

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 guanidine (1:1)	593-84-0	>= 30 - < 50
Poly(oxy-1,2-ethanediyl), .alpha.-dodecyl-.omega.-hydroxy-	9002-92-0	>= 1 - < 5
Sodium citrate dihydrate	6132-04-3	>= 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 : Move to fresh air.

		If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty. If on skin, rinse well with water. If on clothes, remove clothes.
In case of eye contact	:	Small amounts splashed into eyes can cause irreversible tissue damage and blindness. In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Continue rinsing eyes during transport to hospital. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	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. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	Harmful if swallowed. Causes serious eye damage. Causes severe burns.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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) Carbon monoxide Carbon dioxide (CO2) Sodium oxides May release combustible and toxic gases

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

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	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. Dispose of rinse water in accordance with local and national regulations. To prevent leaks or spillages from spreading, provide a suitable liquid retention system.
Conditions for safe storage	:	Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
Materials to avoid	:	Keep away from oxidizing agents, strongly alkaline and strongly acid materials in order to avoid exothermic reactions.
Further information on	:	No decomposition if stored and applied as directed.

storage stability

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 : colorless

Odor : none

Odor Threshold	:	No data available
pH	:	4.0
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	:	1.131 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	:	Hazardous decomposition products formed under fire conditions.
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.

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	:	Toxic gases may be released if in contact with the following: Acids Strong oxidizing agents No decomposition if stored and applied as directed.
Conditions to avoid	:	No data available
Incompatible materials	:	Strong acids Strong oxidizing agents Cyanides sodium hypochlorite
Hazardous decomposition products	:	In case of fire hazardous decomposition products may be produced such as: Carbon oxides Nitrogen oxides (NOx) Sulfur oxides Hydrogen cyanide (hydrocyanic acid)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 1,361 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 26.19 mg/l Exposure time: 4 h Test atmosphere: vapor Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: 2,547 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 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): 1,000 mg/kg Method: OECD Test Guideline 423 GLP: yes
Acute dermal toxicity	:	LD50 Dermal (Rat, male and female): > 2,000 mg/kg Method: OECD Test Guideline 402 GLP: yes

Sodium citrate dihydrate:

Acute oral toxicity	:	LD50 Oral (Mouse): 5,400 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 Dermal (Rat, male and female): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity Remarks: No mortality observed at this dose. The value is given in analogy to the following substances: Citric acid

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
Exposure time	:	4 h
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

GLP : yes

Sodium citrate dihydrate:

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

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-:

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

Sodium citrate dihydrate:

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

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Components:

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

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

Sodium citrate dihydrate:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
Test substance	:	anhydrous substance

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

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

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

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

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

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

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

Sodium citrate dihydrate:

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

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

Genotoxicity in vivo : Test Type: dominant lethal test
Species: Rat
Application Route: Oral
Method: Regulation (EC) No. 440/2008, Annex, B.22
Result: negative

Test Type: Chromosome aberration test in vitro
Species: Rat
Cell type: Bone marrow
Application Route: Oral
Method: OECD Test Guideline 475
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.

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

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

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

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

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

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

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

Aspiration toxicity

Not classified due to lack of data.

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 : EC50 (Daphnia): 42.4 mg/l

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

Ecotoxicology Assessment

Chronic aquatic toxicity	:	Harmful to aquatic life with long lasting effects.
Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

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

Toxicity to fish	:	LC50 (Salmo salar (Atlantic salmon)): 1.5 mg/l End point: mortality Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 6.46 mg/l Exposure time: 48 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0.144 mg/l Exposure time: 21 d Method: QSAR
Toxicity to microorganisms	:	(Photobacterium phosphoreum): 2.5 mg/l Test Type: EC50

Ecotoxicology Assessment

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

Sodium citrate dihydrate:

Toxicity to fish	:	LC50 (Poecilia reticulata (guppy)): > 18,000 - 32,000 mg/l

Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 5,600 - 10,000 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Chlorella vulgaris (Fresh water algae)): 18,000 - 32,000 mg/l
Exposure time: 96 h

Toxicity to microorganisms : EC50 (Bacteria): 1,800 - 3,200 mg/l
Exposure time: 8 h

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

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

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

Sodium citrate dihydrate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

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

Partition coefficient: n-octanol/water : log Pow: -1.11 (77 °F / 25 °C)
pH: > 5.1
Method: Regulation (EC) No. 440/2008, Annex, A.8

GLP: no

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

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

Sodium citrate dihydrate:

Bioaccumulation : Bioconcentration factor (BCF): 3.2
Remarks: Based on data from similar materials

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

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

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

SECTION 14. TRANSPORT INFORMATION

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 : 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

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
Thiocyanic acid, compd. with guanidine (1:1)	593-84-0

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

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

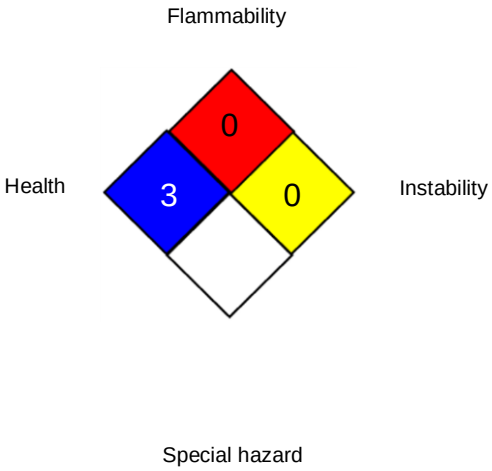
No substances are subject to a Significant New Use Rule.

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

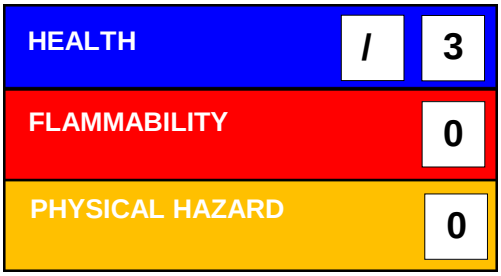
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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 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 : 08-29-2024

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 / 2304

SECTION 1. IDENTIFICATION

Product name : LMP

Manufacturer or supplier's details

Company name of supplier	:	Roche Diagnostics Deutschland GmbH
Address	:	116 Sandhoferstrasse Mannheim, 68305 Deutschland
Telephone	:	+496217590
Telefax	:	+496217592890
E-mail address	:	info.dia-sds@roche.com
Emergency telephone Im Notfall:	:	Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203
Giftnotruf:	:	Mainz +49(0)6131-19240

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	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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	:	Local authorities should be advised if significant spillages cannot be contained.

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

Respiratory protection	:	No personal respiratory protective equipment normally required.
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

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Color	:	brown
Odor	:	none
Odor Threshold	:	No data available
pH	:	6 - 7
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
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 g/cm3
Solubility(ies)		
Water solubility	:	partly miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-	:	No data available

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.

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 dangerous reaction known under conditions of normal use. Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	No data available
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

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.

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.

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:

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).

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. 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.

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
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

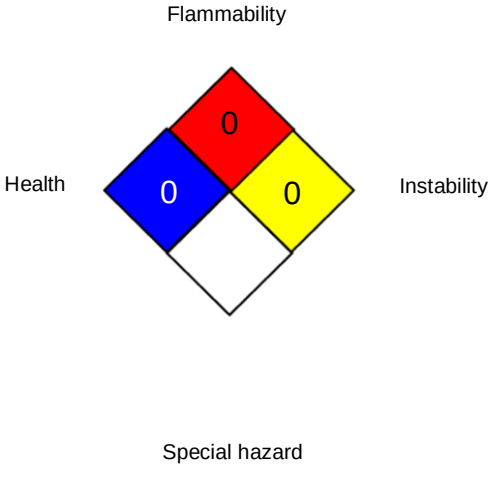
No substances are subject to a Significant New Use Rule.

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

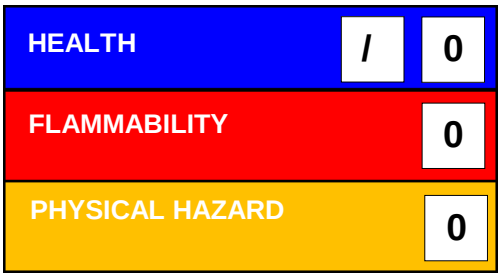
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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 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 : 08-29-2024

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 / 2304

SECTION 1. IDENTIFICATION

Product name : PROK

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse
Mannheim, 68305
Deutschland

Telephone : +496217590
Telefax : +496217592890
E-mail address : info.dia-sds@roche.com
Emergency telephone
Im Notfall: : Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203

Giftnotruf: : Mainz +49(0)6131-19240

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 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	>= 50 - < 70
Proteinase K	39450-01-6	>= 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

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.
Move to fresh air.
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. 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	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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. Local authorities should be advised if significant spillages cannot be contained.
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.

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 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 : In the case of vapor formation use a respirator with an approved filter.

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

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

Appearance : liquid

Color : colorless

Odor : No data available

Odor Threshold : No data available

pH : 7.5

Melting point/range : < -58 °F / < -50 °C

Boiling point/boiling range : 221 °F / 105 °C

Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	The product is not flammable., Does not sustain combustion.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
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	:	1.133 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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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	:	Temperatures greater than recommended storage temperature.
Incompatible materials	:	None.
Hazardous decomposition products	:	Stable under recommended storage conditions.

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

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
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

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
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
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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

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

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 GLP: no
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Daphnia magna (Water flea)): 1,955 mg/l End point: mortality Exposure time: 48 h

Test Type: static test
Analytical monitoring: no
GLP: no

Toxicity to algae/aquatic plants : (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l
End point: Growth rate
Exposure time: 8 d
Test Type: static test
GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10,000 mg/l
End point: Growth rate
Exposure time: 16 h
Test Type: static test
GLP: No information available.

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

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 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-octanol/water	:	log Pow: -1.75 (77 °F / 25 °C) 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-octanol/water	:	log Pow: -4.3 (77 °F / 25 °C) 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 + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

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

SECTION 14. TRANSPORT INFORMATION

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 : 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	>= 50 - < 70 %

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

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

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. 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

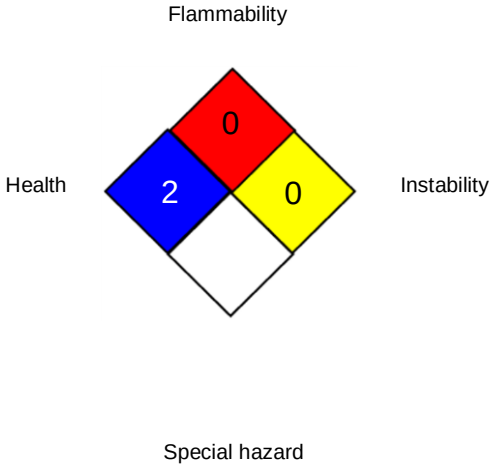
No substances are subject to a Significant New Use Rule.

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

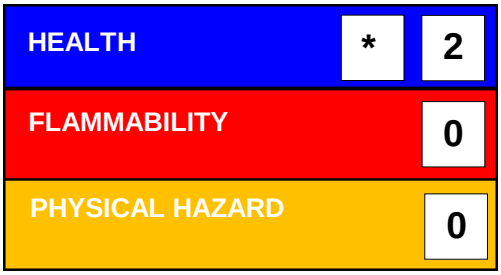
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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

- 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 : 08-29-2024

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US / Z8 / 2304

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Version	Revision Date:	Date of last issue: 08-29-2024
1.4	08-29-2024	Date of first issue: 10-26-2020

SECTION 1. IDENTIFICATION

Product name : IC

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : 116 Sandhoferstrasse
Mannheim, 68305
Deutschland

Telephone : +496217590
Telefax : +496217592890
E-mail address : info.dia-sds@roche.com
Emergency telephone
Im Notfall: : Werkschutzzentrale Roche Diagnostics GmbH +49(0)621-759-2203

Giftnotruf: : Mainz +49(0)6131-19240

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	>= 30 - < 50

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice	:	Do not leave the victim unattended.
If inhaled	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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.
Environmental precautions	:	Local authorities should be advised if significant spillages

cannot be contained.

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

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material	:	Protective gloves
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	:	Handle in accordance with good industrial hygiene and safety 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	:	No data available
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
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.

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
Hazardous decomposition products	:	No data available

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.

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
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

Aspiration toxicity

Not classified due to lack of data.

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 GLP: no
Toxicity to daphnia and other	:	LC50 (Daphnia magna (Water flea)): 1,955 mg/l

aquatic invertebrates		End point: mortality Exposure time: 48 h Test Type: static test Analytical monitoring: no GLP: no
Toxicity to algae/aquatic 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

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

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. 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

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	>= 30 - < 50 %

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-ethanediylbis[N-(carboxymethyl)-	60-00-4	>= 0.1 - < 1 %

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

Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-	60-00-4	>= 0.1 - < 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

Pennsylvania Right To Know

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

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. Glycols Modified alkyl carboxylate 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

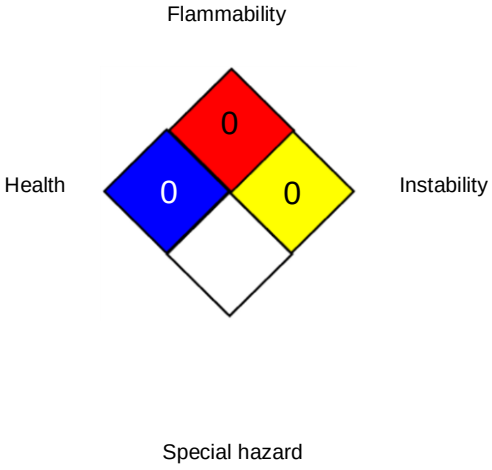
No substances are subject to a Significant New Use Rule.

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

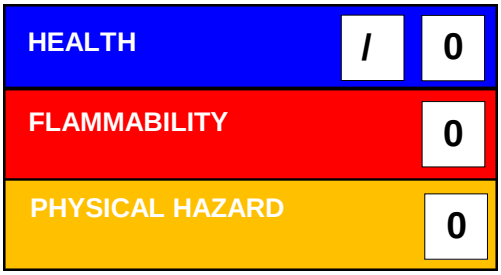
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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

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