

SAFETY DATA SHEET



RNase Inhibitor rec. GMP Grade AOF

Version
1.2

Revision Date:
06/24/2024

Date of last issue: 04/25/2022
Date of first issue: 12/08/2021

SECTION 1. IDENTIFICATION

Product name : RNase Inhibitor rec. GMP Grade AOF

Product code : 09537643103

Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics Deutschland GmbH

Address : Sandhoferstrasse
Mannheim, 68305, Deutschland

Telephone : +496217590

Telefax : +496217592890

E-mail address : info.dia-sds@roche.com

Emergency telephone

Im Notfall: : Werkschutzzentrale Roche +49(0)621-759-2203
Diagnostics GmbH

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 Hazardous Products Regulations

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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
1,2,3-Propanetriol	Glycerol	56-81-5	>= 30 - < 60 *

* Actual concentration or concentration range is withheld as a trade secret

RNase Inhibitor rec. GMP Grade AOFVersion
1.2Revision Date:
06/24/2024Date of last issue: 04/25/2022
Date of first issue: 12/08/2021

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 measures	: Refer to protective measures listed in sections 7 and 8.
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RNase Inhibitor rec. GMP Grade AOF

Version
1.2

Revision Date:
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Date of last issue: 04/25/2022
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agency procedures

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)	10 mg/m ³	CA BC OEL
		TWA (Respirable mist)	3 mg/m ³	CA BC OEL
		TWA (Mist)	10 mg/m ³	CA AB OEL
		TWAEV (Mist)	10 mg/m ³	CA QC OEL

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:

SAFETY DATA SHEET



RNase Inhibitor rec. GMP Grade AOF

Version
1.2

Revision Date:
06/24/2024

Date of last issue: 04/25/2022
Date of first issue: 12/08/2021

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

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

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 : No data available

Odor Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

RNase Inhibitor rec. GMP Grade AOFVersion
1.2Revision Date:
06/24/2024Date of last issue: 04/25/2022
Date of first issue: 12/08/2021

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	:	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.

RNase Inhibitor rec. GMP Grade AOFVersion
1.2Revision Date:
06/24/2024Date of last issue: 04/25/2022
Date of first issue: 12/08/2021

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.

RNase Inhibitor rec. GMP Grade AOFVersion
1.2Revision Date:
06/24/2024Date of last issue: 04/25/2022
Date of first issue: 12/08/2021**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.

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

RNase Inhibitor rec. GMP Grade AOFVersion
1.2Revision Date:
06/24/2024Date of last issue: 04/25/2022
Date of first issue: 12/08/2021Duration of Single Treatment: 29 d
Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day
GLP: no**STOT-single exposure**

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity**Components:****1,2,3-Propanetriol:**

Species	: Rat, male and female
NOAEL	: 4580 mg/kg
NOAEL	: 4,580 mg/kg
Application Route	: Oral
Exposure time	: 90 d
Number of exposures	: daily
Dose	: 4580 - 25,800 mg/kg/day
GLP	: no

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

Species	: Rat
NOAEL	: 5040 mg/kg
NOAEL	: 5,040 mg/kg
Application Route	: Dermal
Exposure time	: 45 Weeks
Number of exposures	: 8 hours/day, 5 days/week
Dose	: 0.5-4.0 ml/kg
GLP	: no

Repeated dose toxicity - Assessment	: Mild eye irritant, Mild respiratory irritant, No skin irritation
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Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****1,2,3-Propanetriol:**

RNase Inhibitor rec. GMP Grade AOFVersion
1.2Revision Date:
06/24/2024Date of last issue: 04/25/2022
Date of first issue: 12/08/2021

- 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

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:**

SAFETY DATA SHEET



RNase Inhibitor rec. GMP Grade AOF

Version
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Revision Date:
06/24/2024

Date of last issue: 04/25/2022
Date of first issue: 12/08/2021

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

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
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

TDG

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

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.

RNase Inhibitor rec. GMP Grade AOFVersion
1.2Revision Date:
06/24/2024Date of last issue: 04/25/2022
Date of first issue: 12/08/2021

RNase Inhibitor

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

Canadian lists

No substances are subject to a Significant New Activity Notification.

SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

CA AB OEL	: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	: Canada. British Columbia OEL
CA QC OEL	: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
CA AB OEL / TWA	: 8-hour Occupational exposure limit
CA BC OEL / TWA	: 8-hour time weighted average
CA QC OEL / TWAEV	: Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-

RNase Inhibitor rec. GMP Grade AOFVersion
1.2Revision Date:
06/24/2024Date of last issue: 04/25/2022
Date of first issue: 12/08/2021

centration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECL - 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; WHMIS - Workplace Hazardous Materials Information System

Revision Date : 06/24/2024
Date format : mm/dd/yyyy

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.

CA / Z8 / 2304