# SAFETY DATA SHEET

## RNase Inhibitor rec. GMP Grade AOF,100kU

| Version | Revision Date: | Date of last issue: 12/08/2021 |
|---|---|---|
| 1.1 | 04/25/2022 | Date of first issue: 12/08/2021 |

### SECTION 1. IDENTIFICATION

Product name : RNase Inhibitor rec. GMP Grade AOF,100kU

Product code : 09537643103

Other means of identification : No data available

**Manufacturer or supplier's details**

Company name of supplier : Roche Diagnostic Canada
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Address : 201 Boulevard Armand-Frappier
Laval, QC, H7V 4A2, Canada

Telephone : 1-877-273-3433
Telefax : 1-877-686-1598
E-mail address : laval.techinfo@roche.com
Emergency telephone
In case of emergencies: : CHEMTREC 1-800-424-9300

Centre for detoxification: : Canadian Association of Poison Control Centres http://www.capcc.ca

**Recommended use of the chemical and restrictions on use**

Restrictions on use : For professional users only.

### SECTION 2. HAZARDS IDENTIFICATION

**GHS classification in accordance with the Hazardous Products Regulations**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**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

### SECTION 4. FIRST AID MEASURES

| | | |
|---|---|---|
| General advice | : | Do not leave the victim unattended. |
| If inhaled | : | Move to fresh air.<br>If unconscious, place in recovery position and seek medical advice.<br>If symptoms persist, call a physician. |
| In case of skin contact | : | If on skin, rinse well with water. |
| In case of eye contact | : | Immediately flush eye(s) with plenty of water.<br>Remove contact lenses.<br>Protect unharmed eye.<br>If eye irritation persists, consult a specialist. |
| If swallowed | : | Keep respiratory tract clear.<br>Do not give milk or alcoholic beverages.<br>Never give anything by mouth to an unconscious person.<br>If symptoms persist, call a physician.<br>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.<br>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) | 10 mg/m3 | CA BC OEL |
| | | TWA (Respirable mist) | 3 mg/m3 | CA BC OEL |
| | | TWA (Mist) | 10 mg/m3 | CA AB OEL |
| | | TWAEV (Mist) | 10 mg/m3 | 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:

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

Remarks : The selected protective gloves have to satisfy the specificati-

ons 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 breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

| | | |
|---|---|---|
| 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 |
| 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.<br>Stable under recommended storage conditions.<br>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 based on available information.

**Components:**

**glycerol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LC50 (Mouse): 11,500 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat, male): 275000 mg/m3<br>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 based on available information.

**Components:**

**glycerol:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**glycerol:**

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

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**glycerol:**

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

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**glycerol:**

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

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

**Carcinogenicity**

Not classified based on available information.

**Components:**

**glycerol:**

| | | |
|---|---|---|
| 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 based on available information.

**Components:**

**glycerol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation study<br>Species: Rat, male and female<br>Application Route: Oral<br>Dose: 2000 mg/kg bw/day<br>Fertility: NOAEL: 2,000 mg/kg body weight<br>GLP: no |
| Effects on fetal development | : | Species: Rabbit, female<br>Application Route: Oral<br>Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day<br>Duration of Single Treatment: 29 d<br>Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day<br>GLP: no |

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity**

**Components:**

**glycerol:**

| | | |
|---|---|---|
| Species | : | Rat, male and female |
| NOAEL | : | 4580 mg/kg |
| NOAEL | : | 4,580 mg/kg |

| | | |
|---|---|---|
| Application Route | : | Oral |
| Exposure time | : | 90 d |
| Number of exposures | : | daily |
| Dose | : | 4580 - 25,800 mg/kg/day |
| GLP | : | no |

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

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 5040 mg/kg |
| 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 based on available information.

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**glycerol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l<br>End point: mortality<br>Exposure time: 96 h<br>Test Type: static test<br>GLP: no |
| Toxicity to daphnia and other aquatic invertebrates | : | LC50 (Daphnia magna (Water flea)): 1,955 mg/l<br>End point: mortality<br>Exposure time: 48 h<br>Test Type: static test<br>Analytical monitoring: no<br>GLP: no |
| Toxicity to algae/aquatic plants | : | (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l<br>End point: Growth rate<br>Exposure time: 8 d<br>Test Type: static test<br>GLP: no |

| | | |
|---|---|---|
| Toxicity to microorganisms | : | EC50 (Pseudomonas putida): > 10,000 mg/l<br>End point: Growth rate<br>Exposure time: 16 h<br>Test Type: static test<br>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:**

**glycerol:**

| | | |
|---|---|---|
| Biodegradability | : | aerobic<br>Inoculum: activated sludge<br>Concentration: 226 mg/l<br>Result: Readily biodegradable.<br>Biodegradation: 94 %<br>Exposure time: 24 h<br>GLP: no |

**Bioaccumulative potential**

**Components:**

**glycerol:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: -1.75 (25 °C)<br>pH: 7.4<br>Method: OECD Test Guideline 107<br>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 | : | 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 | : | Not in compliance with the inventory |
| TCSI | : | On the inventory, or in compliance with the inventory |
| TSCA | : | Product contains substance(s) not listed on TSCA inventory. |
| TECI | : | Not in compliance with the inventory |

**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 Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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; 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; WHMIS - Workplace Hazardous Materials Information System

| | | |
|---|---|---|
| Revision Date | : | 04/25/2022 |
| 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 guid-

ance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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