

# SAFETY DATA SHEET

## SECTION 1) IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1 Product Identifier:

**Product ID:** A17622-PK-1536, A17622-PK-250, A17622-PK-50, A17622-PK-10, A17622-PK  
**Revision Date:** Oct 01, 2025

**Product Name:** Apostle MiniMax High Efficiency Cell-Free DNA Proteinase K (Kit Component)  
**Version:** 6.2

**1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
**Date Printed:** Dec 19, 2025

Life science laboratory use. For research use only.  
**Supersedes Date:** Dec 22, 2025

### 1.3 Details of the Supplier of the Safety Data Sheet:

**Manufacturer's Name:** Roche Diagnostics  
**Address:** 9115 HAGUE RD., INDIANAPOLIS, IN 46250, U.S.

**Information Phone Number:** +1 800-428-5074

**Fax:**

### 1.4 Emergency telephone number:

**Emergency Phone:** Chemtrec +1 800-424-9300 (in the US); +1 703-527-3887 (Outside the US)

## SECTION 2) HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

Respiratory Sensitizer (Solid/Liquid) - Category 1

Skin Sensitizer - Category 1

Safety data sheet prepared in accordance to Regulation (EC) No. 1907/2006 as amended from time to time.

### 2.2 Label Elements

Contains Proteinase K.

#### Pictograms



#### Signal Word

Danger

#### Hazardous Statements - Health

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H317 - May cause an allergic skin reaction

#### Precautionary Statements - General

#### Precautionary Statements - Prevention

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.

P280 - Wear protective gloves, protective clothing, eye protection/face protection.

#### Precautionary Statements - Response

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P333 + P313 - If skin irritation or a rash occurs: Get medical advice/attention.

P362 + P364 - Take off contaminated clothing. And wash it before reuse.

### Precautionary Statements - Storage

### Precautionary Statements - Disposal

#### 2.3 Other hazards

The substance(s) is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

## SECTION 3) COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Not applicable.

### 3.2 Mixtures

CAS	Chemical Name	GHS Classifications	% By Weight	EC No
0039450-01-6	PROTEINASE K	Eye Irr. 2, H319; Resp. Sens. 1, H334; Skin Irr. 2, H315; Skin Sens. 1, H317; STOT SE 3 (Resp.), H335	2% - 4%	254-457-8

Specific chemical identity and/or exact percentage (concentration) of the composition has been withheld to protect confidentiality.

## SECTION 4) FIRST-AID MEASURES

### 4.1 Description of first aid measures

#### Inhalation

Remove source of exposure or move person to fresh air and keep comfortable for breathing.

If breathing is difficult, trained personnel should administer emergency oxygen if advised to do so by the POISON CENTER/doctor.

Call a POISON CENTER/doctor if you feel unwell.

#### Eye Contact

If eye irritation persists:

Get medical advice/attention.

Avoid direct contact. Wear chemical protective gloves, if necessary.

Rinse eyes cautiously with lukewarm, gently flowing water for several minutes, while holding the eyelids open.

Remove contact lenses, if present and easy to do.

Continue rinsing for a duration of 15-20 minutes.

Take care not to rinse contaminated water into the unaffected eye or onto the face.

#### Skin Contact

Take off contaminated clothing, shoes and leather goods (e.g. watchbands, belts).

Wash with plenty of lukewarm, gently flowing water for a duration of 15-20 minutes.

If skin irritation or a rash occurs:

Get medical advice/attention.

Wash contaminated clothing before re-use or discard.

#### Ingestion

Rinse mouth.

If you feel unwell/If concerned:

Get medical advice/attention.

#### 4.2 Most important symptoms and effects, both acute and delayed

No data available.

#### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment should be supportive and based on the judgement of the physician in response to the reaction of the patient.

## SECTION 5) FIRE-FIGHTING MEASURES

### 5.1 Extinguishing media

#### Suitable Extinguishing Media

Small Fire : Dry chemical, foam, carbon dioxide, water-spray or alcohol-resistant foam. Carbon dioxide can displace oxygen. Use caution when applying carbon dioxide in confined spaces. Large Fire : Water spray, fog or alcohol-resistant foam.

#### Unsuitable Extinguishing Media

Do not use straight stream of water.

### 5.2 Special hazards arising from the substance or mixture

Dense smoke may be generated while burning.

### 5.3 Advice for firefighters

#### Fire-fighting Procedures

Isolate immediate hazard area and keep unauthorized personnel out. Stop spill/release if it can be done safely. Move undamaged containers from immediate hazard area if it can be done safely. Cool containers with flooding quantities of water until well after fire is out. Caution should be exercised when using water or foam as frothing may occur, especially if sprayed into containers of hot, burning liquid. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

#### Special Protective Actions

Wear protective pressure self-contained breathing apparatus (SCBA) and full turnout gear.

## SECTION 6) ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### Emergency Procedure

Isolate hazard area and keep unauthorized personnel away. Stay uphill and/or upstream. Ventilate closed spaces before entering. Do not touch damaged containers or spilled materials unless wearing appropriate protective clothing.

#### Personal Precautions

Do not breathe vapor or mist. Do not get on skin, eyes or clothing.

#### Recommended Equipment

Wear chemical protective clothing and positive pressure self-contained breathing apparatus (SCBA). Breathing protection is required.

### 6.2 Environmental Precautions

Stop spill/release if it can be done safely. Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems and natural waterways by using sand, earth, or other appropriate barriers.

### 6.3 Methods and Materials for Containment and Cleaning up

Absorb Liquids in vermiculite, dry sand, earth, or similar inert material and deposit in sealed containers for disposal. Ventilate area after clean-up is complete.

### 6.4 Reference to other sections

See section 8 for specifics on protective personal equipment (PPE). Concerning disposal elimination after cleaning, see section 13.

## SECTION 7) HANDLING AND STORAGE

## 7.1 Precautions for safe handling

### General

Wash hands after use. Do not breathe vapor or mist. Use good personal hygiene practices. Eating, drinking and smoking in work areas is prohibited. Remove contaminated clothing and protective equipment before entering eating areas. Eyewash stations and showers should be available in areas where this material is used and stored. All containers must be properly labelled. Do not get in eyes, on skin, or on clothing.

## 7.2 Conditions for safe storage, including any incompatibilities

### Storage Room Requirements

Store in a cool, dry, well ventilated area, away from sources of ignition and incompatibilities. Keep containers securely sealed when not in use. Containers that have been opened must be carefully resealed to prevent leakage. Empty containers retain residue and may be dangerous.

### Ventilation Requirements

Use only with adequate ventilation to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Report ventilation failures immediately.

## 7.3 Specific end use(s)

No data available.

## SECTION 8) EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Chemical Name	UK_WELmg - United Kingdom Workplace Exposure Limits TWA Long-term exposure limit (8-hour Time-Weighted Average) mg/m3	UK_WELppm - United Kingdom Workplace Exposure Limits TWA Long-term exposure limit (8-hour Time-Weighted Average) ppm	UK_WELsmg - United Kingdom Workplace Exposure Limit STEL Short-term exposure limit (15-minutes) mg/m3	UK_WELsppm - United Kingdom Workplace Exposure Limit STEL Short-term exposure limit (15-minutes) ppm	UK_WEL_Health - United Kingdom Workplace Exposure Standard Health Effects	UK_WEL_Notes - United Kingdom Workplace Exposure Standard Notes	EU_IOELV - European Indicative Occupational Exposure Limit Value	ACGIH_Carcinogen_Threshold - Threshold for ACGIH Carcinogens
GLYCEROL	10							

Chemical Name	UK_WEL - United Kingdom Workplace Exposure Limits	ACGIH	ACGIH TWA (mg/m3)	ACGIH TWA (ppm)	ACGIH STEL (mg/m3)	ACGIH STEL (ppm)	ACGIH Carcinogen	ACGIH TLV Basis
GLYCEROL	1							

Chemical Name	ACGIH Notations	IOELV TWA (mg/m3)	IOELV TWA (ppm)	IOELV STEL (mg/m3)	IOELV STEL (ppm)	IOELV Notations	IOELV Directive
GLYCEROL							

### 8.2 Exposure Controls

#### Eye protection

Wear indirect-vent, impact and splash resistant goggles when working with liquids. If additional protection is needed for entire face, use in combination with a face shield. Goggles should be consistent with EN 166B or equivalent. The lens must remain in the frame and is not to shatter. The frame must remain intact as well. Frame and lens must withstand the impact of a 6 mm steel ball weighing 0,86 gram fired at 432 km/h.

#### Skin Protection

Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Use of chemical resistant gloves classified under Standard EN374: Protective gloves against chemicals and microorganisms. Examples of preferred glove barrier materials include: Butyl rubber, Polyethylene, Chlorinated polyethylene, Ethyl vinyl

alcohol laminate ("EVAL"). Examples of acceptable glove barrier materials include: Viton, Neoprene, Polyvinyl chloride ("PVC" or "vinyl"), Nitrile/butadiene rubber ("nitrile" or "NBR"). Suitability and durability of a glove is dependent on usage, e.g. frequency and duration of contact, chemical resistance of glove material, glove thickness, dexterity. When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended. When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended. Full contact Material: butyl-rubber Minimum layer thickness: 0.3 mm Break through time: 480 min Material tested: Butoject® (KCL 897 / Aldrich Z677647, Size M). Splash contact Material: Nitrile rubber Minimum layer thickness: 0.4 mm Break through time: 30 min Material tested: Camatril® (KCL 730 / Aldrich Z677442, Size M). Considering the parameters specified by the glove manufacturer check during use that the gloves are still retaining their protective properties. Contaminated gloves should be replaced. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

### Respiratory protection

If engineering controls do not maintain airborne concentrations to a level which is adequate to protect worker, a respiratory protection program should be followed. When workers are facing concentrations above the occupational exposure limits they must use appropriate certified respirators. When atmospheric levels may exceed the occupational exposure limit (PEL or TLV) certified air-purifying respirators equipped with EN 14387 certified organic vapor absorbent and particulate filter (Filter Type A) can be used as long as appropriate precautions and change out schedules are in place. For emergency or non-routine, high exposure situations, including confined space entry, use certified full facepiece pressure demand self-contained breathing apparatus (SCBA) or a full facepiece pressure demand supplied-air respirator (SAR) with escape provisions.

### Appropriate Engineering Controls

Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value.

### Environmental Exposure Control

Use the appropriate container to avoid environmental contamination. Keep away from all drains, surface, and ground water. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

## SECTION 9) PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Density	1.14 g/cm <sup>3</sup>
Specific Gravity	1.14
% VOC	0.00%
Density VOC	0.00 g/cm <sup>3</sup>
% HAPS	0.00%
Density HAPS	0.00 g/cm <sup>3</sup>
% VHAPS	0.00%
Density VHAPS	0.00 g/cm <sup>3</sup>
% Solids By Weight	63.50%

Refractive Index	N/A
Appearance	Clear liquid
Odor Threshold	N/A
Odor Description	Odorless
pH	6.5 - 8
Water Solubility	N/A
Flammability	Will not burn
Flash Point Symbol	N/A
Flash Point	N/A
Viscosity	N/A
Lower Explosion Level	N/A
Upper Explosion Level	N/A
Vapor Pressure	N/A
Vapor Density	N/A
Freezing Point	N/A
Melting Point	N/A
Low Boiling Point	N/A

High Boiling Point	N/A
Auto Ignition Temp	N/A
Decomposition Pt	N/A
Evaporation Rate	N/A
Kinematic Viscosity	N/A
Kinematic Viscosity Temperature	N/A
Coefficient Water/Oil	N/A
Flame Extension	N/A
Water Content	N/A

## 9.2 Other Information

No Data Available.

## SECTION 10) STABILITY AND REACTIVITY

### 10.1 Reactivity

No data available.

### 10.2 Chemical Stability

Stable under normal storage and handling conditions.

### 10.3 Possibility of Hazardous Reactions

No data available. Will not occur.

### 10.4 Conditions To Avoid

Avoid heat, sparks, flame and contact with incompatible materials

### 10.5 Incompatible Materials

Strong bases, acids, and oxidizing agents.

### 10.6 Hazardous Decomposition Products

Oxides of carbon.

## SECTION 11) TOXICOLOGICAL INFORMATION

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

#### Acute Toxicity

The Acute Toxicity Estimate (ATE) for an oral exposure to this mixture is >5000 mg/kg body weight

The Acute Toxicity Estimate (ATE) for a dermal exposure to this mixture is >5000 mg/kg body weight

The Acute Toxicity Estimate (ATE) for an inhalation (vapour) exposure to this mixture is >20 mg/l

#### Aspiration Hazard

Based on available data, the classification criteria are not met.

#### Carcinogenicity

Based on available data, the classification criteria are not met.

#### Germ Cell Mutagenicity

Based on available data, the classification criteria are not met.

#### Reproductive Toxicity

Based on available data, the classification criteria are not met.

#### Respiratory/Skin Sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled

May cause an allergic skin reaction

#### Serious Eye Damage/Irritation

Based on available data, the classification criteria are not met.

#### **Skin Corrosion/Irritation**

Based on available data, the classification criteria are not met.

#### **Specific Target Organ Toxicity - Repeated Exposure**

Based on available data, the classification criteria are not met.

#### **Specific Target Organ Toxicity - Single Exposure**

Based on available data, the classification criteria are not met.

#### **Likely Routes of Exposure**

Inhalation, Ingestion, Skin contact, Eye contact

### **11.2 Information on other hazards**

#### **11.2.1 Endocrine disrupting properties**

Adverse health effects caused by endocrine disrupting properties : No data available.

#### **11.2.2 Other Information**

Other information : Symptoms related to the physical, chemical and toxicological characteristics, for further information see section 4.

## **SECTION 12) ECOLOGICAL INFORMATION**

### **12.1 Toxicity**

Based on available data, the classification criteria are not met.

### **12.2 Persistence and degradability**

No data available.

### **12.3 Bioaccumulative Potential**

No data available.

### **12.4 Mobility in Soil**

No data available.

### **12.5 Results of the PBT and vPvB assessment**

No data available.

### **12.6 Endocrine Disrupting Properties**

The substance(s) is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

### **12.7 Other Adverse Effects**

No data available.

### **12.8 Additional Information**

No data available.

## **SECTION 13) DISPOSAL CONSIDERATIONS**

### **13.1 Waste Treatment Methods**

Product/Packaging disposal recommendations : Avoid release to the environment. Dispose of empty containers and wastes safely. See Section 7 for information on safe handling. Refer to manufacturer/supplier for information on recovery/recycling. Recycling is preferred to disposal or incineration. If recycling is not possible, eliminate in accordance with local valid waste disposal regulations. Handle contaminated packages in the same way as the substance itself. Dispose of contaminated materials in accordance with current regulations. European waste catalogue (2001/573/EC, 75/442/EEC, 91/689/EEC) : This material and its container must be disposed of as hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

### **13.2 Waste Disposal**

#### **Waste Treatment Methods**

It is the responsibility of the user of the product to determine at the time of disposal whether the product meets local criteria for hazardous

waste. Waste management should be in full compliance with national, state and local laws.

## SECTION 14) TRANSPORT INFORMATION

	Land Transportation (ADR/RID)	Inland Waterway Transport (ADN(R))	Air Transport (ICAO/IATA)	Marine Transport (IMDG)
14.1 UN Number	Not Regulated	Not Regulated	Not Regulated	Not Regulated
14.2 UN proper shipping name	N/A	N/A	N/A	N/A
14.3 Transport Hazard class(es)	Not Applicable	Not Applicable	Not Applicable	Not Applicable
14.4 Packing group	Not Applicable	Not Applicable	Not Applicable	Not Applicable
14.5 Environmental hazards	No Data Available	No Data Available	No Data Available	No Data Available
14.6 Special precautions for user	No Data Available	No Data Available	No Data Available	No Data Available
14.7 Maritime transport in bulk according to IMO instruments	No Data Available	No Data Available	No Data Available	No Data Available

## SECTION 15) REGULATORY INFORMATION

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1 EU REACH Regulations

Contains no REACH Annex XIV substances.

Contains no substance on the REACH candidate list at a concentration level  $\geq 0.1\%$ .

EU Regulations:

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments. REACH 1907/2006 EC – Annex XVII – Restrictions on Certain Dangerous Substances. Microplastic information: Use restricted. See entry 78.

#### 15.1.2 National Regulations

No additional information available.

### 15.2 Chemical Safety Assessment

No Data Available.

CAS	Chemical Name	% By Weight	Regulation List
0000056-81-5	GLYCEROL	42% - 66%	EU_EINECS - European_EC_Inventory_EINECS, EU_EC_Inventory - European Inventory
0007732-18-5	WATER	26% - 40%	EU_EINECS - European_EC_Inventory_EINECS, EU_EC_Inventory - European Inventory
0039450-01-6	PROTEINASE K	1% - 4%	EU_EINECS - European_EC_Inventory_EINECS, EU_EC_Inventory - European Inventory

The information in this Section does not list non-hazardous components that might have relevant EU\_EC\_Inventory - European Inventory, EU\_EINECS - European\_EC\_Inventory\_EINECS regulatory values, if they are present at less than 1%. Please contact manufacturer for more information.

## SECTION 16) OTHER INFORMATION

### Glossary

ACGIH - American Conference of Governmental Industrial Hygienists; Acute Tox. - acute toxicity; ADN - (European Agreement concerning the

International Carriage of Dangerous Goods by Inland Waterways; ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road; CAS - Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances); Chemtrec - Chemical Transportation Emergency Center; CLP Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures; DSL - Domestic Substances List; EC No - The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union) EH40/2005 EH40/2005 Workplace exposure limits (<http://www.nationalarchives.gov.uk/doc/opengovernment-licence/>); EINECS - European Inventory of Existing Commercial Chemical Substances; ELINCS - European List of Notified Chemical Substances; Eye Dam. - Seriously damaging to the eye; Eye Irrit. – Irritant to the eye; Flam. Liq. – Flammable Liquid; Flam. Sol. – Flammable Solid; GHS - "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations; HMIS - Hazardous Material Information Service; IATA - Dangerous Goods Regulations (DGR) for the air transport (IATA); IMDG - International Maritime Dangerous Goods Code; MARPOL - International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant"); IOELV - Indicative Occupational Exposure Limit Value; LC - Lethal Concentration; LD - Lethal Dose; NFPA - National Fire Protection Association; OEL - Occupational Exposure Limits; NLP - No-Longer Polymer; PBT - Persistent, Bioaccumulative and Toxic; PEL - Permissible Exposure Limit; SARA 313 - Superfund Amendments and Reauthorization Act, Section 313; SCBA - Self Contained Breathing Apparatus; ppm - parts per million; REACH - Registration, Evaluation, Authorization and Restriction of Chemicals; Resp. Sens. - Respiratory sensitization; Resp. – Respiratory Irritation; RID - (Regulations concerning the International carriage of Dangerous goods by Rail; Skin Corr. - Corrosive to skin; Skin Irrit. - Irritant to skin; Skin Sens. - Skin sensitization; STEL - Short-term exposure limit; STOT SE - Specific target organ toxicity - single exposure; TLV - Threshold Limit Value; TSCA - Toxic Substances Control Act Public Law 94-469; TWA - Time-weighted average; vPvB - Very Persistent and very Bioaccumulative; WEL - Workplace exposure limit.

### Training advice

Training staff on good practice. Manipulations are to be done only by qualified and authorized persons.

### Classification methods used to derive the classification for mixtures according to Regulation (EC) 1272/2008

Calculation methods have been used for evaluation of all hazard classes assigned to the product under Article 9 of Regulation (EC) No. 1272/2008.

### Key literature references and sources for data

ECHA Dissemination Database, ECHA (European Chemicals Agency), Supplier SDS, INCHEM, ECOTOX (Ecotoxicology Knowledgebase), RTECS (Registry of Toxic Effects of Chemical Substances).

### Classification methods used to derive the classification for mixtures according to Regulation (EC) 1272/2008

Calculation methods have been used for evaluation of all hazard classes assigned to the product under Article 9 of Regulation (EC) No. 1272/2008.

### Version 6.2:

Revision Date: Oct 01, 2025

### Full text of H-Statements referred to under Section 3

- H319 Causes serious eye irritation
- H315 Causes skin irritation
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H317 May cause an allergic skin reaction
- H335 May cause respiratory irritation

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### DISCLAIMER

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