according to Regulation (EC) No. 1907/2006



# **Enzyme Mix**

(EliGene® COVID19 UKV/SAV RT, 90083-RT, 90083-RT-500, EliGene® COVID19 BASIC A RT, 90077-RT, 90077-RT-500, EliGene® COVID19 CONFIRM RT, 90078-RT, 90083-RT-500, EliGene® COVID19 Delta RT, 90086-RT, 90086-RT-500, EliGene® COVID19 Omicron Lite RT, 90087-RT-500, EliGene® COVID19 Omicron RT, 90087-RT, 90087-RT-500, EliGene® COVID19 TRIPLE RIC RT, 90079-RT, 90079-RT-500, EliGene® COVID19 UKV RT, 90082-RT, 90082-RT-500, EliGene® Enterovirus LC, 90053-LC, EliGene® HCV LC, 90059-LC, EliGene® Influenza A/B/Pandemic, 90058-LC, EliGene® Norovirus LC, 90054-LC, EliGene® TBEV LC, 90070-LC, EliGene® Tick-borne diseases RT, 90091-RT)

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

# 1.1 Product identifier:

Commercial Product Name: Enzyme Mix

(EliGene® COVID19 UKV/SAV RT, 90083-RT, 90083-RT-500 EliGene® COVID19 BASIC A RT, 90077-RT, 90077-RT-500 EliGene® COVID19 CONFIRM RT, 90078-RT, 90083-RT-500 EliGene® COVID19 Delta RT, 90086-RT, 90086-RT-500 EliGene® COVID19 Omicron Lite RT, 90088-RT, 90088-RT-500 EliGene® COVID19 Omicron RT, 90087-RT, 90087-RT-500 EliGene® COVID19 TRIPLE RIC RT, 90079-RT, 90079-RT-500 EliGene® COVID19 UKV RT, 90082-RT, 90082-RT-500

EliGene® Enterovirus LC, 90053-LC

EliGene® HCV LC, 90059-LC

EliGene® Influenza A/B/Pandemic, 90058-LC

EliGene® Norovirus LC, 90054-LC EliGene® TBEV LC, 90070-LC

EliGene® Tick-borne diseases RT, 90091-RT)

REACH No.: This product is a mixture. REACH Registration Number see section 3.

# 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture: Laboratory chemicals not in a nanoform

# 1.3 Details of the supplier of the safety data sheet

Company: ELISABETH PHARMACON, spol. s r.o.

Rokycanova 4437/5, 615 00 Brno,

Czech Republic

Telephone: +420 542 213 851 E-mail: info@elisabeth.cz

# 1.4 Emergency telephone number

Centre for Detoxification Prague: +420 224 91 92 93/ +420 224 91 54 02

# **SECTION 2: HAZARDS IDENTIFICATION**

### 2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

# 2.2 Label elements

Precautionary statements (P statements)

P280+P281 Wear protective gloves/protective clothing/eye protection/face protection.

Use personal protective equipment as required.

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#### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative, and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher or having endocrine disruptor properties.

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

#### 3.1 Mixtures

Hazardous components

Remarks: Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008

#### **SECTION 4: FIRST AID MEASURES**

### 4.1 Description of first aid measures

General advice: Show this data sheet to the doctor in attendance.

If inhaled: Move to fresh air.

If symptoms persist, call a physician.

In case of skin contact: Wash off immediately with soap and plenty of water while removing all

contaminated clothes and shoes. If symptoms persist, call a physician.

In case of eye contact: Remove contact lenses.

Protect unharmed eyes.

Rinse thoroughly with plenty of water for at least 15 minutes and consult a

physician.

If swallowed: If accidentally swallowed obtain immediate medical attention.

Rinse mouth with water.

Never give anything by mouth to an unconscious person.

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

Symptoms: No information available.

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

Treatment: No information available.

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

# 5.1 Extinguishing media

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

circumstances and the surrounding environment.

# 5.2 Special hazards arising from the substance or mixture

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Specific hazards during firefighting: Exposure to decomposition products may be a hazard to health.

Hazardous combustion products: No hazardous combustion products are known

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus for firefighting if

necessary.

Further information: In the event of fire and/or explosion do not breathe fumes.

### **SECTION 6: ACCIDENTAL RELEASE MEASURES**

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

Personal precautions: Use personal protective equipment.

Avoid breathing dust/fume/gas/mist/vapours/spray.

#### 6.2 Environmental precautions

## 6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

For personal protection see section 8.

# **SECTION 7: HANDLING AND STORAGE**

### 7.1 Precautions for safe handling

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

Smoking, eating and drinking should be prohibited in the

application area.

Advice on protection against

Normal measures for preventive fire protection.

fire and explosion:

Hygiene measures: Keep away from food and drink. When using do not eat, drink or

smoke.

### 7.2 Conditions for safe storage, including any incompatibilities

Other data: No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s): Laboratory chemicals

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

# 8.1 Control parameters

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Contains no substances with occupational exposure limit values.

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### 8.2 Exposure controls

a) Physical state

Personal protective equipment

Eye protection: Safety glasses

Hand protection Remarks: The choice of an appropriate glove does not only depend on its

material but also on other quality features and is different from one producer to the other. Take note of the information given by the producer concerning permeability and break through times, and of

special workplace conditions (mechanical strain, duration of

contact).

Skin and body protection: Choose body protection according to the amount and

concentration of the dangerous substance at the work place.

Footwear protecting against chemicals

Liquid

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

# 9.1 Information on basic physical and chemical properties

b) Color	No data available
c) Odor	No data available
d) Melting point/freezing point	No data available
e) Initial boiling point and boiling range	No data available
f) Flammability (solid, gas)	No data available
g) Upper/lower flammability or explosive limits	No data available
h) Flash point	No data available
i) Autoignition temperature	No data available
j) Decomposition temperature	No data available
k) pH	No data available
I) Viscosity Viscosity, kinematic:	No data available
Viscosity, dynamic:	No data available
m) Water solubility at 20 °C	soluble
n) Partition coefficient: n-octanol/water	No data available
o) Vapor pressure	No data available
p) Density	No data available
Relative density	No data available
q) Relative vapor density	No data available

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r) Particle characteristics No data available

s) Explosive properties Not classified as explosive.

t) Oxidizing properties none

### 9.2 Other safety information

No data available

# **SECTION 10. STABILITY AND REACTIVITY**

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

# 10.3 Possibility of hazardous reactions

Violent reactions are possible with:

The generally known reaction partners of water.

# 10.4 Conditions to avoid

no information available

# 10.5 Incompatible materials

Strong bases, Strong oxidizing agents

# 10.6 Hazardous decomposition products

In the event of fire: see section 5.

## **SECTION 11. TOXICOLOGICAL INFORMATION**

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

## Mixture

# **Acute toxicity**

Oral: No data available Inhalation: No data available Dermal: No data available **Skin corrosion/irritation** 

No data available

# Serious eye damage/eye irritation

No data available

# Respiratory or skin sensitization

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No data is available.

# Germ cell mutagenicity

No data available

# Carcinogenicity

No data available

### Reproductive toxicity

No data available

#### 11.2 Information on other hazards

Assessment: The substance/mixture does not contain components considered to have endocrine-disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

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

# 12.1 Toxicity

Toxicity to fish:

Toxicity to algae:

No data available

No data available

No data available

No data available

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

Bioaccumulation: No data available

# 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB Assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative, and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

# 12.6 Endocrine-disrupting properties

Assessment: The substance/mixture does not contain components considered to have endocrine-disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

# 12.7 Other adverse effects

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Additional ecological information Remarks: No data available

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

### 13.1 Waste treatment methods

Contaminated packaging: Empty containers should be taken to an approved waste handling

site for recycling or disposal.

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

#### 14.1 UN number or ID number

ADR/RID: - IMDG: - IATA: -

### 14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

# 14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

# 14.4 Packing group

ADR/RID: - IMDG: - IATA: -

### 14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

#### 14.6 Special precautions for user

No data available

# 14.7. Maritime transport in bulk according to IMO instruments

No data available

# **SECTION 15. REGULATORY INFORMATION**

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

### **15.2 Chemical Safety Assessment**

For this product a chemical safety assessment was not carried out

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

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### Full text of other abbreviations

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ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC -Australian Inventory of Industrial Chemicals; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; 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

#### **Further information**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product regarding appropriate safety precautions. It does not represent any guarantee of the properties of the product. Elisabeth Pharmacon company shall not be held liable for any damage resulting from handling or from contact with the above product.