

SECTION 1 Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product trade name: gb SARS-CoV-2 Combi
Components: Component Assay CoV-2 E-RdRP Combi (0.5 ml), Component Master Mix OneStep Multi (1.0 ml), Component Positive Control CoV-2 (0.2 ml), Component EPC Template RNA (1.0 ml) Component Deionized Water (1 ml)

Catalogue no.: 3232-100, 3232-500

1.2. Relevant purposes of use of the substance or mixture and non-recommended use

Use of the substance or mixture: SU 0-2 Other economic activity not related to chemical substances.
PC 21 Laboratory chemicals
PROC 15 Use as laboratory reagent

Non-recommended use: All use other than recommended.

1.3. Detailed information about the material safety data sheet supplier**Supplier identification:**

Business name: GENERI BIOTECH s.r.o.
Address: Hradec Králové 11 - Třebeš, Machkova 587/42, Post code 50011
Identification no.: 632 21 667
Telephone no.: 495 056 314
E-mail: info@generi-biotech.com

1.4. Emergency telephone numbers

Medical rescue emergency: 155
Fire rescue emergency: 150
Police: 158
European emergency line: 112

Toxicological information center:

Tel.: +420 224 919 293; +420 224 915 402
Residence: Klinika pracovního lékařství 1. LF UK a VFN, Na Bojišti 1, 120 00 Praha 2

SECTION 2 Hazards identification**2.1. Classification of the mixture****Classification of the mixture in accordance with Regulation (EC) 1272/2008:**

Hazardous feature: Not known.
H-Phrases: Not assigned.

The most important physicochemical effects:

Not known.

The most important negative effects on human health:

Not known.

The most important negative effects on environment:

Not known.

Components classification in accordance with Regulation (EC) 1272/2008:**Component Assay CoV-2 E-RdRP Combi**

Hazardous feature: Not known.
H-Phrases: Not assigned.

The most important physicochemical effects:

Not known.

The most important negative effects on human health:

Not known.

The most important negative effects on environment:

Not known.

Component Master Mix OneStep Multi

Hazardous feature: Not known.

H-Phrases: Not assigned.

The most important physicochemical effects:

Not known.

The most important negative effects on human health:

Not known.

The most important negative effects on environment:

Not known.

Component Positive Control CoV-2

Hazardous feature: Not known.

H-Phrases: Not assigned.

The most important physicochemical effects:

Not known.

The most important negative effects on human health:

Not known.

The most important negative effects on environment:

Not known.

Component EPC Template RNA

Hazardous feature: Not known.

H-Phrases: Not assigned.

The most important physicochemical effects:

Not known.

The most important negative effects on human health:

Not known.

The most important negative effects on environment:

Not known.

Component Deionized Water

Hazardous feature: Not known.

H-Phrases: Not assigned.

The most important physicochemical effects:

Not known.

The most important negative effects on human health:

Not known.

The most important negative effects on environment:

Not known.

2.2. Label elements**Classification of a mixture in accordance with Regulation (EC) 1272/2008:**

Warning sign: Not assigned.

Signal word: Not assigned.
 H-Phrases: Not assigned.
 P-Phrases: Not assigned.

Components classification in accordance with Regulation (EC) 1272/2008:

Component Assay CoV-2 E-RdRP Combi

Warning sign: Not assigned.
 Signal word: Not assigned.
 H-Phrases: Not assigned.

Component Master Mix OneStep Multi

Warning sign: Not assigned.
 Signal word: Not assigned.
 H-Phrases: Not assigned.

Component Positive Control SARS-CoV-2

Warning sign: Not assigned.
 Signal word: Not assigned.
 H-Phrases: Not assigned.

Component EPC Template RNA

Warning sign: Not assigned.
 Signal word: Not assigned.
 H-Phrases: Not assigned.

Component Deionized Water

Warning sign: Not assigned.
 Signal word: Not assigned.
 H-Phrases: Not assigned.

2.3. **Other hazards**

Not known.

SECTION 3 Composition/Information on ingredients

3.1. **Substances**

Product name:

Registration Number:

Other identification data of hazardous substances:

Index Number CAS EC number Registration Number	Chemical name	Concentration (% weight)	Classification in accordance with EC 1272/2008
-	-	-	-

3.2. **Mixtures**

Product name: gb SARS CoV-2 Combi

Catalogue number: 3232-100, 3232-500

Other identification data of hazardous substances:

Ingredient name	Index number CAS EC number Registration	Chemical name	Concentration (% weight)	Classification in accordance with EC 1272/2008
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	number			
Assay CoV-2 E-RdRP Combi (0.5 ml)	-	Contains no hazardous substances	0.1 - 1	Not classified
Master Mix OneStep Multi (1.0 ml)	-	Contains no hazardous substances	0.1 - 1	Not classified
Positive Control SARS-CoV-2 (0.2 ml)	-	Contains no hazardous substances	0.1 - 1	Not classified
EPC Template RNA (1.0 ml)				
Deionized Water (1 ml)	-	Contains no hazardous substances	0.1 - 1	Not classified

SECTION 4 First aid measures

4.1. Description of first aid measures

General information:

Symptomatic treatment.

In case of inhalation:

Remove the person afflicted to fresh air, keep him/her calm, warm and in comfortable position. In case of breathing difficulties ensure medical help.

In case of contact with skin:

Remove contaminated clothing. Wash irritated skin with warm water for 15 minutes. If difficulties persist, seek medical help.

In case of contact with eyes:

Rinse eyes with sufficient amount of water for at least 15 minutes while lifting both upper and lower eyelids. If difficulties persist, seek medical help.

In case of ingestion:

Do not induce vomiting. Wash out mouth and drink larger amount of water. In case of health difficulties seek medical help. Do not administer anything orally to unconscious person.

Protection of first aid providers:

Based on the extent of the provided aid it is necessary to use protective equipment.

Other data:

Further details about providing first aid, especially in severe cases, may be consulted with Toxicological information center, **non-stop telephone line:** 224 919 293, 224 915 402, fax 224 914 570.

4.2. The most important acute and delayed symptoms and effects

Risk for eyes: Not known.

Risk in case of contact with skin: Not known.

Risk in case of ingestion: Not known.

Risk in case of inhalation: Not known.

4.3. Directions regarding immediate medical help and special treatment

See point 4.1

SECTION 5 Firefighting measures

5.1. Extinguishing media

Product is not flammable.

Suitable extinguishing media: Use extinguishing media appropriate for the type of fire and surrounding conditions – foam, fragmented water stream, dry powder, carbon dioxide.

Unsuitable extinguishing media: Full water stream – fire could spread.

5.2. Special hazards arising from substance or mix

Hazardous combustion products: carbon dioxide, carbon monoxide, nitrogen oxides, water vapour.

5.3. Advice for firefighters

Use complete chemically resistant protective overall and breathing apparatus.

SECTION 6 Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****6.1.1 For non-emergency personnel:**

Protective equipment: Use personal protective equipment – safety gloves, safety goggles, protective clothing and footwear.

Emergency procedures: In case of spilling or fire evacuate the area. Prevent access of unauthorized people.

6.1.2 For emergency personnel:

Protective equipment: In case of spilling or fire use complete protective overall and breathing apparatus.

6.2. Environmental precautions

Prevent leakage into soil, surface and ground water and sewage.

6.3. Methods and material for containment and cleaning up**6.3.1 Methods for containment:**

Store in a resealable container. In case of spilling prevent entering drains.

6.3.2 Cleaning up methods:

Dust with absorbent non-flammable substance (vermiculite, sand, soil etc.) and collect mechanically. Place the used sorbent into suitable container and mark it as a waste. Dispose of in accord with valid waste management regulations.

Disposal - see SECTION 13

6.4. Reference to sections

Detailed information is available in sections 8 and 13.

SECTION 7 Handling and storage**7.1. Precautions for safe handling****7.1.1 Safety measures**

Fire precautions: The product is non-flammable.

Precautions for prevention of aerosol and dust forming: Ensure sufficient ventilation of workplace.

Environmental precautions: Prevent release into the environment.

7.1.2 Directions regarding general work hygiene

Respect safety rules and use protective means when manipulating the substance. Do not inhale vapours and aerosols. Do not eat, drink or smoke while at workplace. Wash your hands and face when finished working. Wash stained clothing and clean footwear before next use. Apply regenerating cream on your hands.

7.2. Conditions for safe substance and mixture storage, including incompatible substances and mixtures

Technical precautions and storage conditions: The original GENERI BIOTECH packaging ensures safe storage. Respect storage requirements stated on the packaging. Keep the product away from food, beverages, fodders and medications.

Packaging materials: Store in closed and properly marked container.

Requirements for storage space and storage containers: Storage space must meet valid legal requirements.

Other information about storage conditions:

Not known.

7.3. Specific end use(s)

See SECTION 1.2.

SECTION 8 Exposure controls / Personal protection

8.1. Control parameters

Component Assay CoV-2 E-RdRP Combi (0.5 ml) – Contains no substances with occupational exposure limit values in the workplace.

Component Master Mix OneStep Multi (1.0 ml) – Contains no substances with occupational exposure limit values in the workplace.

Component Positive Control SARS-CoV-2 (0.2 ml) – Contains no substances with occupational exposure limit values in the workplace.

Component EPC Template RNA (1.0 ml) – Contains no substances with occupational exposure limit values in the workplace.

Component Deionized Water (1 ml) – Contains no substances with occupational exposure limit values in the workplace.

8.2. Exposure control

8.2.1 Suitable technical controls:

Precautions for exposure control while using substance/mixture: Store in closed container. Install proper room ventilation in workplace and storage space. Prevent contact with eyes and skin. Use personal protective means. Do not eat, drink or smoke at workplace where the product is handled. Always wash your hands when finished working.

Technical measures for exposure control: Ensure effective ventilation of workplace.

8.2.2 Personal protective means:

8.2.2.1 Eyes and face protection

Safety goggles.

8.2.2.2 Skin protection

Hands protection: Safety gloves (PVC, latex, neoprene)

Other skin protection: protective clothing and footwear

8.2.2.3 Respiratory protection

Not a possible way of exposure.

8.2.2.4 Thermal hazard

The mixture is non-flammable.

8.2.3 Environmental exposure control

Prevent soil and water contamination.

SECTION 9 Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Appearance:	liquid
Odour:	non perceptible
Odour threshold:	not applicable
pH:	not determined
Melting point/Freezing point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	not determined
Evaporation rate:	not determined
Flammability (solid, gas):	not determined
Upper/lower flammability limits:	not determined
Vapour pressure:	not determined
Vapour density:	not determined
Relative density:	not determined
Solubility:	not determined
Partition coefficient n-octanol/water:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not determined
Explosive properties:	not determined
Oxidising properties:	not determined

9.2. Other information

not available

SECTION 10 Stability and reactivity**10.1. Reactivity**

The substance is non-reactive in normal conditions.

10.2. Chemical stability

The substance is stable in normal conditions.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

Not known.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition products

Not known.

SECTION 11 Toxicological information**11.1. Information on toxicological effects**

Acute toxicity:	not determined
Skin corrosion/irritation:	not determined
Serious eye damage/irritation:	not determined
Respiratory or skin sensitisation:	not determined
Germ cell mutagenicity:	not determined
Carcinogenicity:	not determined
Reproductive toxicity:	not determined
STOT-single exposure:	not determined
STOT-repeated exposure:	not determined
Aspiration hazard:	not determined

Information on likely routes of exposure: not determined

Symptoms related to the physical, chemical and toxicological characteristics:

not known

Delayed and immediate effects as well as chronic effects from short and long-term exposure:

not known

SECTION 12 Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined.

12.4. Mobility in soil

Not determined.

12.5. Results of PBT and vPvB assessment

Not determined.

12.6. Other adverse effects

Not determined.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

13.1.1 Product/container disposal:

Product disposal methods: The product must be disposed of in accordance with valid and effective waste management law and related legal regulations.

Contaminated container disposal methods: The container must be disposed of in accordance with valid and effective waste management law and related legal regulations.

Other information: All waste must be handed over to a subject licensed for waste management. Waste marking must correspond with valid identifiers stated in waste catalogue.

13.1.2 Important information for waste management:

Residues of the substance and container should be treated as a waste.

SECTION 14 Transport information

The product is safe for transport.

14.1. UN number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

-

14.5. Environmental hazards

-

14.6. Special precautions for user

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14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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SECTION 15 Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Act No. 350/2011 Coll. (Czech Republic) on chemicals and chemical mixtures.

Act No. 541/2020 Coll. (Czech Republic) on waste, as amended.

Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, as amended.

Commission Regulation (EU) No. 453/2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

European Parliament and of the Council Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures, as amended.

Regulation (EU) No 2015/830 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Act No. 93/2012 Coll. (Czech Republic), amending Act No. 361/2007 Coll., which states health protection conditions, as amended by Act No. 68/2010 Coll.

Regulation No. 8/2021 Coll. (Czech Republic) waste catalogue and assessment of waste properties, as amended

Regulation No. 273/2021 Coll. (Czech Republic) on waste management details, as amended.

15.2. Chemical safety assessment

Not executed yet.

SECTION 16 Other information**16.1 Training instructions:**

Inform employees about the content of this safety data sheet and about general rules concerning treatment of chemicals and formulations. Carry out training at least once a year.

16.2 Important literature and data source references

Registered substances database ECHA, as of 19 August 2021
Valid legal regulations

16.3 Abbreviations:

PBT	Persistent, bioaccumulative and toxic
vPvB	Highly persistent and highly bioaccumulative
REACH	Registration, evaluation, authorization and restriction of chemical substances
ECHA	European chemical agency
PEL	Permissible exposure limit
NPK-P	Highest permissible concentration
PVC	Polyvinyl chloride

16.4 Other information

Information provided in this safety data sheet is based on the state of manufacturer's knowledge and experience as of the date of issue of this document. It does not represent any contract guarantee on product's qualitative features and is valid only in connection with usual manipulation under normal conditions and with data specified in technical manual. Any other use of this product, eventually in combination with other products and methods, is user's own responsibility.