

Safety data sheet (SDS)

according to Regulation (EC) No. 1907/2006 (REACH) Article 32



Date of issue: 14.12.2022

Version: 2

DBdirect COVID-19 Multiplex RT-PCR Kit

Section 1: Identification of the substance and company

1.1 Product identifier

Product name: DBdirect COVID-19 Multiplex RT-PCR Kit
Catalogue number: DB-1219
Package contents: Enhancer mix (4x)
Primer mix (4x)
Enzyme mix (4x)
Positive control
Negative control
External control
Manufacturer: DIANA Biotechnologies, s.r.o.
Address: Vestec, 25250, Nad Safinou II 366

1.2 Relevant intended uses of the substance or mixture and non-recommended uses

Intended uses: Laboratory chemicals, diagnostic kit

1.3 Details of the safety data sheet company

Trade name: DIANA Biotechnologies, s.r.o.
Head office: Nad Safinou II 366, 25250 Vestec
Czech Republic
Telephone number: +420 212 247 462
E-mail: support@dianabiotech.com
www: <http://www.dianabiotech.com>

1.4 Emergency telephone number

Toxikologické informační středisko, Na Bojišti 1, 128 21 Prague. Emergency telephone:
+420 224 91 92 93/ +420 224 91 54 02, www.tis-cz.cz

Section 2: Hazards identification

2.1 Substance or mixture identification

Classification according to Regulation (EC) No. 1272/2008 (CLP):
Not subject to classification

2.2 Labelling elements

Labelling according to Regulation (EC) No. 1272/2008 (CLP):
Warning symbol: None

Signal word: None

2.3 Other hazards

The mixture and its components are not classified as PBT or vPvB, are not on the candidate list for Annex XIV of REACH (not on the SVHC list) at the date of preparing the datasheet.

Safety data sheet (SDS)

according to Regulation (EC) No. 1907/2006 (REACH) Article 32



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Section 3: Composition/Information on ingredients

3.1 Substances

Mixture

3.1.1 Ingredients of the mixture classified as hazardous

Enhancer mix (4x)

None of the components of the mixture is classified as hazardous according to Regulation (EC) No. 1272/2008 (CLP).

Primer mix (4x)

None of the components of the mixture is classified as hazardous according to Regulation (EC) No. 1272/2008 (CLP).

Enzyme mix (4x)

None of the components of the mixture is classified as hazardous according to Regulation (EC) No. 1272/2008 (CLP).

Positive control

None of the components of the mixture is classified as hazardous according to Regulation (EC) No. 1272/2008 (CLP).

External control

None of the components of the mixture is classified as hazardous according to Regulation (EC) No. 1272/2008 (CLP).

Negative control:

None of the components of the mixture is classified as hazardous according to Regulation (EC) No. 1272/2008 (CLP).

Section 4: First aid measures

4.1 General instructions

If you come into contact with the substance, follow first aid instructions and workplace standards.

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

Symptomatic treatment.

Section 5: Fire-fighting measures

5.1 Extinguishing media

Dry powder, dry sand, water, CO2

5.2 Special hazards arising from the substance or mixture

None.

5.3 Advice for firefighters

When extinguishing, use a closed-circuit breathing apparatus if necessary.

Safety data sheet (SDS)

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DBdirect COVID-19 Multiplex RT-PCR Kit

Date of issue: 14.12.2022

Version: 2

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes, contamination of clothing and footwear. Wear appropriate personal protective equipment. Ensure ventilation of the affected area.

6.2 Environmental precautions

Prevent further leakage or spillage unless there is a risk involved. Prevent leakage into the environment. Avoid entry into sewers.

6.3 Methods and materials for containment and cleaning up

Soak up the leaked fluid with an inert absorbent. Wash contaminated surfaces and tools with plenty of water.

6.4 Reference to other sections

See sections 7, 8 and 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Do not eat, drink or smoke while working. Wash hands after work.

7.2 Conditions for safe storage, including any incompatibilities

Store the containers according to the manufacturer's instructions in the manual and on the packaging. Store at the temperature specified in the manual and on the packaging in a vertical position.

7.3 Specific end use(s)

See section 1.2.

Section 8: Exposure controls/personal protection

8.1 Control parameters

Exposure limits:

Contains no substances with occupational exposure limit values.

Biological limits:

Contains no hazardous materials with biological limits set by regional regulatory authorities.

DNEL:

No data available.

PNEC:

No data available.

8.2 Exposure controls

Technical measures:

Technical precautions and appropriate working practices take precedence over personal protective equipment. Observe normal principles of hygiene. Do not eat, drink or smoke while working. Wash hands with warm water and soap before and after work breaks.

Individual protective measures

Safety data sheet (SDS)

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DBdirect COVID-19 Multiplex RT-PCR Kit

Respiratory protection:

It is not necessary if the specified concentration limits are observed and if there is no formation of vapours, mists or aerosols. If concentration limits are exceeded or if vapours, mists and aerosols are formed, use a suitable respirator against organic vapours (e.g. type A1) or protective breathing apparatus independent of the ambient air.

Hand protection:

Protective gloves according to EN ISO 374 (e.g. made of nitrile rubber, thickness 0.11 mm, penetration time 480 min). Use protective hand cream before work.

Eyes and face protection:

If splashing is likely, use: safety glasses with side covers.

Skin protection:

Protective work clothing and footwear.

Limiting environmental exposure:

Prevent unnecessary releases into the environment.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties.

Cannot be used.

9.2 Other information

Cannot be used.

Section 10: Stability and reactivity

10.1 Reactivity

It is not expected under the correct conditions of use.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions are not known.

10.4 Conditions to avoid

Comply with the handling and storage conditions set out in Section 7.

10.5 Materials to avoid

Strong oxidizing agents, strong acids, strong bases.

10.6 Hazardous decomposition products

Hazardous decomposition products are not known.

Section 11: Toxicological information

11.1 Information on toxicological effects

The product does not meet the criteria for classification.

Section 12: Ecological information

12.1 Toxicity

The product does not meet the criteria for classification.

12.2 Persistence and degradability

The product does not meet the criteria for classification.

Safety data sheet (SDS)

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12.3 Bioaccumulative potential

The product does not meet the criteria for classification.

12.4 Mobility in soil

The product does not meet the criteria for classification.

12.5 Other adverse effects

The product does not meet the criteria for classification.

Section 13: Disposal considerations

13.1 Waste treatment methods

The recommended waste mixture disposal procedure.

Dispose of in accordance with local regulations.

The recommended procedure for disposal of waste packaging contaminated with mixtures.

Dispose of in accordance with local regulations.

Section 14: Transport information

ADR

Not regulated, no dangerous goods.

IMDG

Not regulated, no dangerous goods.

ICAO/IATA

Not regulated, no dangerous goods.

Section 15: Regulatory information

15.1 Safety, health and environmental regulations/specific legislation relating to the substance or mixture

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Article 32.

15.2 Chemical hazard assessment

No chemical safety assessment has been carried out for this product.

Section 16: Other information

Abbreviations:

| | |
|------|---|
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| CAS | Chemical Abstracts Service |
| DNEL | Derived exposure level without effect (derived no-effect level) |
| IATA | International Air Transport Association |
| ICAO | Technical instructions for the safe carriage of dangerous goods by air |
| IMDG | International Regulation on the Carriage of Dangerous Goods by Sea |
| PNEC | Expected concentration without effect (predicted no-effect concentration) |

Changes from the previous version:

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Modification of the form, unification of all components into one SDS document

Date of preparation:

14.12.2022

Further information:

The above information describes the conditions for the safe handling of the product, corresponds to the current knowledge of the manufacturer and serves as guidelines for the training of persons handling the product.

It is assumed that the above information is correct. However, it does not mean that it is complete and should be used only as a guide. DIANA Biotechnologies, s.r.o is not responsible for damage caused by handling or contact with the chemicals listed. To the fullest extent permitted by law, DIANA Biotechnologies, s.r.o. shall not be liable for any direct or indirect damages associated with or arising out of this document and its use, or for any direct or indirect damages associated with or arising out of the product and its use.

