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**SAFETY DATA SHEET**

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**SECTION 1: Identification**

## 1.1 Product identifier

- Product Name: Genedrive® 96 SARS-CoV-2 Kit
- Product Code: ID-CoV2-01-HPC, ID-CoV2-01-HPU, ID-CoV2-01-LPC, ID-CoV2-01-LPU, ID-CoV2-01-FPC, ID-CoV2-01-FPU, ID-CoV2-01-BPC, ID-CoV2-01-BPU
- Product Description: A 96 well plate containing lyophilised reagent mix in each well

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

- Use of the substance/mixture: The Genedrive® 96 SARS-CoV-2 Kit assay is intended to be used for the qualitative diagnosis of SARS-CoV-2 infection within symptomatic individuals.  
Refer to the Instructions for Use.
- Use advised against: Not for sale to the general public

## 1.3 Product and Company information

- Name of Manufacturer: Genedrive Diagnostics Ltd
- Address of Manufacturer: 48 Grafton Street  
Manchester  
M13 9XX  
UK
- Telephone: +44 (0) 161 989 0245
- Email: support@genedrive.com
- Website: www.genedrive.com
- Genedrive® is a registered trademark of Genedrive plc

## 1.4 Emergency telephone number

- Emergency Telephone: +44 (0) 161 989 0245

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**SECTION 2: Hazard(s) Identification**

## 2.1 Classification of the substance or mixture

- Classification (29 CFR 1910.1200) [HCS 2012]: Not classified
- Additional information: For full text of Hazard Statements: see section 16

## 2.2 Label elements

- Hazard pictograms: None
- Signal Word: None
- Hazard statements  
None
- Precautionary statements  
None

## 2.3 Other hazards

- There are no other hazards not otherwise classified (HNOC) that have been identified

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**SECTION 3: Composition/Information on Ingredients**

## 3.1 Substances

- Not applicable

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**SECTION 3: Composition/Information on Ingredients (....)**

## 3.2 Mixtures

- Contains no hazardous ingredients at levels above the relevant thresholds

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**SECTION 4: First-Aid Measures**

Rescuers should take suitable precautions to avoid becoming casualties themselves

Rescuers should put on approved personal protective equipment (PPE) before administering first aid

## 4.1 Description of first aid measures

- Contact with eyes  
If substance has got into eyes, immediately wash out with plenty of water for several minutes  
Remove contact lenses, if present and easy to do. Continue rinsing.  
If eye irritation persists: Get medical advice/attention.
- Contact with skin  
Gently wash with plenty of soap and water.  
If skin irritation occurs: Get medical advice/attention.
- Ingestion  
Rinse mouth.  
Give plenty of water to drink  
Get medical advice/attention.
- Inhalation  
If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.  
Get medical advice/attention.

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

- Contact with eyes  
May cause eye irritation
- Contact with skin  
May cause skin irritation
- Ingestion  
May cause irritation of the throat  
The ingestion of significant quantities may cause nausea/vomiting
- Inhalation  
May cause respiratory irritation

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

- Treat symptomatically

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**SECTION 5: Fire-Fighting Measures**

## 5.1 Extinguishing media

- Suitable extinguishing media: Not flammable. In case of fire use extinguishing media appropriate to surrounding conditions
- Unsuitable extinguishing media: High volume water jet

## 5.2 Special hazards arising from the substance or mixture

- No information available

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**SECTION 5: Fire-Fighting Measures (....)**

## 5.3 Advice for firefighters

- Fight fire with normal precautions from a reasonable distance.
- Prevent run off water from entering drains if possible

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**SECTION 6: Accidental Release Measures**

## 6.1 Personal precautions, protective equipment and emergency procedures

- No action shall be taken involving any personal risk or without suitable training
- Only trained and authorised personnel should carry out emergency response
- Avoid contact with skin and eyes
- Wear protective clothing as per section 8
- Wash thoroughly after dealing with spillage

## 6.2 Environmental precautions

- Avoid release to the environment.

## 6.3 Methods and material for containment and cleaning up

- Avoid formation of dust
- Wipe up spillage with damp absorbent cloth or towel
- Wash spill site with water and detergent
- Wash thoroughly after dealing with spillage

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**SECTION 7: Handling and Storage**

## 7.1 Precautions for safe handling

- No special precautions are required for this product
- Do not eat, drink or smoke when using this product.
- Wash thoroughly after handling.

## 7.2 Conditions for safe storage, including any incompatibilities

- Keep in a cool, dry place
- Shelf life: refer to the expiry date stated on the label

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**SECTION 8: Exposure Controls/Personal Protection**

## 8.1 Control parameters

- Does not contain any ingredients with a workplace exposure limit

## 8.2 Exposure controls

- Selection and use of personal protective equipment should be based on a risk assessment of exposure potential
- Engineering controls  
Engineering controls are not required for normal handling  
Ensure adequate ventilation
- Respiratory protection  
No respiratory protection is needed during normal handling, if dust is formed, wear a NIOSH-approved dust mask or respirator.
- Eye/face protection  
None required for normal handling of product
- Skin protection  
None required for normal handling of product  
When the material is dissolved or suspended in an organic solvent, wear gloves that provide

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**SECTION 8: Exposure Controls/Personal Protection (....)**

- protection against the solvent.
- Hygiene measures
    - Use good personal hygiene practices
    - Do not eat, drink or smoke when using this product.
    - Wash thoroughly after handling.
  - Environmental exposure controls
    - Do not empty into drains
    - Do not allow to penetrate the ground/soil.
- 

**SECTION 9: Physical and Chemical Properties**

## 9.1 Information on basic physical and chemical properties

- Appearance: Off-white lyophilised powder in a 96 well plate
- Odor: None
- Odor threshold: No information available
- pH: 8.0 – 8.5 (when reconstituted)
- Melting point/freezing point: No information available
- Initial boiling point and boiling range: No information available
- Flash point: Not applicable
- Evaporation Rate: Not applicable
- Flammability (solid,gas): Not applicable
- Upper/lower flammability or explosive limits: Not applicable
- Vapor pressure: No information available
- Vapor density: No information available
- Relative Density: No information available
- Solubility(ies): Soluble in water
- Partition Coefficient (n-Octanol/Water): No information available
- Auto-ignition temperature: No information available
- Decomposition temperature: No information available
- Viscosity: Not applicable

## 9.2 Other information

- No information available
- 

**SECTION 10: Stability and Reactivity**

## 10.1 Reactivity

- No information available

## 10.2 Chemical stability

- Considered stable under normal conditions

## 10.3 Possibility of hazardous reactions

- No hazardous reactions known if used for its intended purpose

## 10.4 Conditions to avoid

- No information available

## 10.5 Incompatible materials

- No information available

## 10.6 Hazardous decomposition products

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**SECTION 10: Stability and Reactivity (....)**

- No information available
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**SECTION 11: Toxicological Information**

## 11.1 Information on toxicological effects

- Acute Toxicity  
Based on available data, the classification criteria are not met
  - Skin corrosion/irritation  
Based on available data, the classification criteria are not met
  - Serious eye damage/irritation  
Based on available data, the classification criteria are not met
  - Respiratory or skin sensitisation  
Based on available data, the classification criteria are not met
  - Germ cell mutagenicity  
Based on available data, the classification criteria are not met
  - Carcinogenicity  
Based on available data, the classification criteria are not met  
None of the components of the product/mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
  - Reproductive toxicity  
Based on available data, the classification criteria are not met
  - Specific target organ toxicity (STOT) - single exposure  
Based on available data, the classification criteria are not met
  - Specific target organ toxicity (STOT) - repeated exposure  
Based on available data, the classification criteria are not met
  - Aspiration hazard  
Based on available data, the classification criteria are not met
  - Contact with eyes  
May cause eye irritation
  - Contact with skin  
May cause skin irritation
  - Ingestion  
May cause irritation of the throat  
The ingestion of significant quantities may cause nausea/vomiting
  - Inhalation  
May cause respiratory irritation
- 

**SECTION 12: Ecological Information**

## 12.1 Toxicity

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

## 12.2 Persistence and degradability

- No information available

## 12.3 Bioaccumulative potential

- No information available

## 12.4 Mobility in soil

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**SECTION 12: Ecological Information (....)**

- No information available

## 12.5 Other adverse effects

- No information available
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**SECTION 13: Disposal Considerations**

## 13.1 Waste treatment methods

- Avoid release to the environment.
  - Disposal should be in accordance with local, state or national legislation
  - Dispose of contents/container to an authorised waste collection point
- 

**SECTION 14: Transport Information**

Not classified as hazardous for transport

## 14.1 UN number or ID number

- UN No.: Not applicable

## 14.2 UN proper shipping name

- Proper Shipping Name: Not applicable

## 14.3 Transport hazard class(es)

- Hazard Class: Not applicable

## 14.4 Packing group

- Packing Group: Not applicable

## 14.5 Environmental hazards

- Not Classified

## 14.6 Special precautions for user

- Not Classified

## 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

- Not Classified

## 14.8 DOT / CFR (US Department of Transportation)

- Proper Shipping Name: Not applicable
- DOT UN No.: Not applicable
- DOT Hazard Class: Not applicable
- DOT Packing Group: Not applicable

## 14.9 Sea (IMDG)

- Proper Shipping Name: Not applicable
- IMDG UN No.: Not applicable
- IMDG Hazard Class: Not applicable
- IMDG Pack Group.: Not applicable

## 14.10 Air (ICAO/IATA)

- Proper Shipping Name: Not applicable
  - ICAO UN No.: Not applicable
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**SECTION 14: Transport Information (....)**

- ICAO Hazard Class: Not applicable
  - ICAO Packing Group: Not applicable
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**SECTION 15: Regulatory Information**

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

- This safety data sheet is prepared according to OSHA Hazard Communication Standard 29 CFR 1910.1200 (HCS 2012)
  - California Proposition 65: No ingredients are listed
  - EPCRA (SARA Title III) Section 313 Table II chemical list: No ingredients are listed
  - TSCA Inventory:
    - CAS 1927-31-7 is not listed on the TSCA inventory. It is for research and development use only.
    - CAS 18423-43-3 is not listed on the TSCA inventory. It is for research and development use only.
    - CAS 93919-41-6 is not listed on the TSCA inventory. It is for research and development use only.
    - CAS 102783-51-7 is not listed on the TSCA inventory. It is for research and development use only.
  - USA State Right-to-Know: No ingredients are listed
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**SECTION 16: Other Information**

The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication, however no guarantee is made to its accuracy. This 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 other process.

Sources of data: ECHA substance databases, GESTIS substance database, eChemPortal

Revision No. 2.0.0. Revised February 2021.

Changes made: Formula changed and edits to all sections

Classification and procedure used to derive the classification for mixtures according to 29 CFR 1910.1200 (HCS 2012):

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

Text not given with phrase codes where they are used elsewhere in this safety data sheet:

- None assigned

## Acronyms

- ACGIH: American Conference of Governmental Industrial Hygienists
- CAS: Chemical Abstracts Service
- GHS: Globally Harmonised System
- IARC: International Agency for Research on Cancer
- NIOSH: The National Institute for Occupational Safety and Health
- NTP: National Toxicology Program
- OEL: Occupational Exposure Limit
- OSHA: Occupational Safety and Health Administration
- WEL: Workplace Exposure Limit

--- end of safety datasheet ---

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