

| Doc Name: | Material Safety Data Sheet (MSDS) for Quantiplus ® HBV FAST RTPCR Kit (Real-Time Quantitative PCR | | |
|-----------|---|-----------|-------------------------|
| | Kit) | | |
| Doc No. | MSDS/HL/008 | Ver No:00 | Effective from: 1/11/23 |

| 1 | Company | HLSS Manufacturing Pvt Ltd | |
|-----|---------------------------|--|--|
| | identification | Plot No's M14, M15, M16, TSIIC Medical device park | |
| | | Sulthanpur villiage, Ameenpur Mandal, Sangareddy Dist, TS-502319 | |
| | | Emergency Contact Tel: +91-08413-232256/ | |
| | | +91 9052226226 | |
| | | Email: <u>info@huwellifesciences.com</u> http://www.huwellifesciences.in | |
| 2 | Product | <u></u> | es.m |
| Z | identification | | |
| 2.1 | Name of the Product | : Quantiplus [®] HBV FAST RTPCR Kit (Real-Time Quantitative PCR Kit) | |
| 2.2 | Product Code | : QTF-HBV-25 QTF-HBV-50 QTF-HBV-100 | |
| 2.3 | Pack size (No. of rxns) | : 25 Tests, 50 Tests, 100 Tests | |
| 2.4 | Intended use: | Quantiplus [®] HBV FAST RT-PCR Kit is a Real-Time PCR based in vitro diagnostic assay for quantitation of Hepatitis B Virus in human plasma. The test is used to monitor the HBV DNA levels in chronic HBV infections and response to antiviral therapy. The kit contains qPCR mix with UDG/UNG, Primer Probe Mix (PPM), Standards (HBVFQS1-HBVFQS4), and Internal Control (IC-B mix). This advanced formulation enables performance of fast PCR in shorter run time (≤60 min), and UDG/UNG helps in controlling PCR carryover contamination. This kit is not to be used for screening of blood/blood products from blood donors. | |
| 2.5 | Composition/ | The product contains genera | al buffer, dNTP's, amplification mix, primer and |
| | Information on | probes and MgCl ₂ with non-hazardous properties. | |
| | reagents: | | |
| | l'agenter | | be used for Invitro Diagnostic Use only. This |
| | | | scientists/ laboratory technicians with strong |
| | | knowledge on molecular biol product insert/ instruction n | logy as per Good Laboratory practice (GLP) and |
| | | | lanual. |
| 3 | Hazards identification | Significant health effects are not anticipated from routine use of this kit when following the precautions listed within this MSDS and the kit specific package insert. None of the components listed within this kit are considered hazardous as defined by the Occupational Safety and Health Administration (OSHA). | |
| | | OSHA Hazards | : No Known OSHA Hazards |
| | | Inhalation | : No information available. |
| | | Ingestion | : May be harmful. |
| | | Skin Contact | : No information available. |
| | | Eye Contact | : May cause irritation. |
| 4 | First-Aid Measures | For all incidents, a medical exam is desirable | |
| - | | , | |

Caution

Page 1 of 3

If you have any further questions about this MSDS, please contact our Technical Support by email: info@huwellifesciences.in



| Doc Name: | Material Safety Data Sheet (MSDS) for Quantiplus ® HBV FAST RTPCR Kit (Real-Time Quantitative PCR | | |
|-----------|---|-----------|-------------------------|
| | Kit) | | |
| Doc No. | MSDS/HL/008 | Ver No:00 | Effective from: 1/11/23 |

| | <u> </u> | Page 2 of 3 |
|------|---|--|
| 12 | Toxicological information | Potential effects on health Eyes : No information available |
| | reactivity | Materials to avoid: No information available Hazardous decomposition Products: No information available |
| 11 | Stability and | investigated Stability: Stable under conditions described in the Product insert |
| 10.1 | Physical state | : Liquid Chemical, physical, and toxicological properties have not been thoroughly |
| 10 | Physical and Chemical properties | |
| 9 | Personnel Protection | Respiratory protection : No information available Hands protection: Wear water-proof gloves Eyes protection : Use chemical safety goggles Skin protection : Wear lab coat Hygiene measures: Follow good laboratory hygiene practices and security Instructions |
| 8.1 | Exposure limits | : No information available |
| 8 | Exposure controls | |
| 6 | Accidental release Measures Handling and storage | Protective equipment For fire fighting: Carry an autonomous respiratory protection apparatus and appropriate protection clothes Individual Precaution: Use an individual protection equipment Environmental Precaution: If incident, let flow run copiously Method of cleaning: Clean with an inert absorbent No specific recommendation is requested. Always store in frozen condition, Observe all conditions described in the user manual and on the labels. As with all chemical and biological substances, avoid getting the components within this kit spilled on you or into your body. Do not eat or drink while using this kit. This kit should be handled only by qualified clinical or laboratory employees trained on the use of this kit and who are familiar with the potential hazards. Universal precautions to be followed when handling and working with this kit. |
| 5 | Fire-fighting Measures | Extinguishing media: Use any mean suitable to extinguish the surrounding fire Un-extinguishing media : No information available Special hazards of product: No information available |
| | | Ingestion: May Induce immediate vomiting, seek medical adviceSkin Contact: Wash copiously with water and soap.Eye Contact: Flush eyes copiously with water and seek medical advice |

Caution

If you have any further questions about this MSDS, please contact our Technical Support by email: info@huwellifesciences.in



| Doc Name: | Material Safety Data Sheet (MSDS) for Quantiplus® HBV FAST RTPCR Kit (Real-Time Quantitative PCR | | |
|-----------|--|-----------|-------------------------|
| | Kit) | | |
| Doc No. | MSDS/HL/008 | Ver No:00 | Effective from: 1/11/23 |

| | | Skin | : No information available |
|----|-------------------|---|--|
| | | Inhalation | : No information available |
| | | | : No information available |
| | | Ingestion | |
| | | Special Effects | |
| | | Carcinogen | : No information available |
| | | Mutagen | : No information available |
| | | Toxicity for reproduction | : No information available |
| | | Sensitization | : No information available |
| 13 | Ecological | Mobility | : No information available |
| | information | Persistence/degradation | : Intrinsically biodegradable |
| | | Bioaccumulation | : No information available |
| | | Aquatic Toxicity | : No information available |
| | | Disposal Considerations & r | equirements : Dispose in accordance with |
| | | state and local regulations | |
| 14 | Transportation | The product is not dangerous. Follow IATA regulations | |
| | information | | |
| 15 | Regulatory | No information available | |
| | information | | |
| 16 | Other Information | ion HLSS Manufacturing Pvt Ltd assumes no liability for damages resulting from handling or being in contact with this product. Customer is solely | |
| | | responsible for improper usage of this product other than for what this | |
| | | product is designed to use. The kit and its components may present | |
| | | unknown hazards and should be used with caution. Improper use and/or | |
| | | inappropriate combination with other products and substances may | |
| | | produce harmful results. | |
| | | -End- | |
| | | | |

Caution

Page 3 of 3

If you have any further questions about this MSDS, please contact our Technical Support by email: info@huwellifesciences.in