

Revision Date: 6 Sept 2024

MATERIAL SAFETY DATA SHEET

Generic MSDS – No Country Specific Data

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY / UNDERTAKING

Product Name : mSEP™ BCR::ABL1 Major dPCR Test

Product Number : **MBCR-RA192/ MBCR-CA192**

Company : Veredus Laboratories Pte Ltd
(Company Registration Number: 200305085G)
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2. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical (1): mSEP™ BCR::ABL1 Major PPM

<u>Composition</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Index No.</u>	<u>Concentration</u>
Oligodeoxyribonucleic Acid (Modified, Non-Radioactive) Classification: Non-hazardous	Not Classified	None	None	–
IDTE Classification: Non-hazardous	Not Classified	None	None	–

Chemical (2): mSEP™ dPCR Nuclease-Free Water

<u>Composition</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Index No.</u>	<u>Concentration</u>
Water (Unmodified) Classification: Non-hazardous	Not Classified	None	None	–

Chemical (3): mSEP™ dPCR Direct RT MM

<u>Composition</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Index No.</u>	<u>Concentration</u>
Glycerin Classification: Non-hazardous	56-81-5	200-289-5	None	40% to 70%

We recommend handling all chemicals with caution

Chemical (4): mSEP™ BCR ::ABL1 Major IS_0.1%

<u>Composition</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Index No.</u>	<u>Concentration</u>
Human Source Material	N/A	N/A	None	0.1%

Classification: hazardous

The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. This product contains human source material (human cells) and should be treated / handled as a potential biohazard. All such human source material has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions

Chemical (5): mSEP™ BCR ::ABL1 Major IS_10%

<u>Composition</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Index No.</u>	<u>Concentration</u>
Human Source Material	N/A	N/A	None	0.1%

Classification: hazardous

The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. This product contains human source material (human cells) and should be treated / handled as a potential biohazard. All such human source material has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions

3. HAZARDS IDENTIFICATION

Risk advice to man and the environment

Irritating to eyes, respiratory system and skin.

The potential health hazards associated with exposure / handling of this mixture are unknown; no data specific for the mixture were identified. The following data describe the hazards of individual ingredients, where applicable. This product contains human source material (human cells) and should be treated / handled as a potential biohazard. All such human source material has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions

4. FIRST AID MEASURE

Inhalation Exposure

If breathed in, move person to area of fresh air. If not breathing, give artificial respiration. If breathing becomes difficult, consult a physician. Immediately notify medical personnel and supervisor

Dermal Exposure

In case of skin contact, remove contaminated clothing, wash affected area with soap and copious amount of water

Oral Exposure

If swallowed, wash out mouth with water provided the person is conscious. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor. Call a physician

Eye Exposure

Rinse eye thoroughly with plenty of flowing water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers. Consult a physician.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Water Spray, Carbon Dioxide, Dry Chemical Powder or Alcohol-resistant foam, as appropriate for surrounding fire and materials

Specific hazards arising from the substance or mixture

No information identified. May emit carbon monoxide and carbon dioxide, and phosphorus-containing compounds.

Flammability/Explosivity

No explosivity or flammability data identified. High airborne concentrations of finely divided organic particles can potentially explode if ignited

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes

Advice for firefighters

In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use

Special Risks

Specific Hazard(s): Emits toxic fumes under fire conditions

6. ACCIDENTAL RELEASE MEASURES

Procedure of Personal Precaution

Exercise appropriate precautions to minimize direct contact with skin or eyes and prevent inhalation of dust. Always wear recommended Personal Protective Equipment. Use personal protection equipment such as gloves during handling of chemical. Area should be adequately ventilated. Do not breathe dust

Methods for Cleaning Up

Avoid raising dust. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations. Ventilate area and wash spill site after material pickup is complete. Decontaminate the area twice with an appropriate solvent

7. HANDLING AND STORAGE

Handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. Normal measures for preventive fire protection. Precautions for safe handling of chemical 4 (mSEP™ BCR ::ABL1 Major IS_0.1%) and 5 (mSEP™ BCR ::ABL1 Major IS_10%) should be handled at the Biosafety Level 2 (BSL2) consistent with the U.S. Department of Health and Human Services, the U.S. Public Health Service, Centers for Disease Control (CDC), and National Institute of Health (NIH) Guidelines "Biosafety in Microbiological and Biomedical Laboratories" (December 2009, HHS Publication No. (CDC) 21-1112). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing dust

Storage

Keep container tightly closed. Store in -30°C to -10°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment

Respiratory Protection

Where risk assessment shows air-purifying respirators are appropriate, use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)

Hand Protection

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with protective gloves

Eye Protection

Chemical safety goggles or Safety glasses

Skin and Body Protection

Choose body protection according to the amount and concentration of the dangerous substance at the workplace

General Hygiene Measure

Wash thoroughly after handling, before breaks and at the end of workday

Engineering Control

Safety shower and eye bath. Mechanical exhaust required

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Form Liquid
Colour Colourless, Light pink

Safety Data

pH Not Determined
Melting point 0°C
Boiling point 100°C
Flash point Not Determined
Ignition temperature Not Determined
Lower explosion limit Not Determined
Upper explosion limit Not Determined
Density Not Determined
Water solubility Soluble in water

Appearance

Form Lyophilized powder
Colour White
Odor No information identified.

Safety Data

pH Not applicable
Melting point No information identified.
Boiling point No information identified.
Flash point No information identified.
Evaporation rate Not applicable.
Flammability (solid, gas) No information identified.
Upper/lower flammability or explosive limits No information identified.
Vapor pressure Not applicable.
Vapor density Not applicable.
Ignition temperature No information identified.
Explosive properties No information identified.
Decomposition temperature No information identified.
Relative Density No information identified.
Water solubility No information identified.
Solvent solubility No information identified.
Partition coefficient (n-octanol/water) No information identified.
Viscosity No information identified.
Oxidizing properties No information identified.

Other information

Molecular formula Not applicable (Mixture)
Molecular weight Not applicable (Mixture)

10. STABILITY AND REACTIVITY

Storage Stability

Stable: Stable under normal condition

Materials to avoid : Strong oxidizing agents, Strong Acid, Potassium, Isocyanate, Ammonia. Base

Hazardous Decomposition Product

Hazardous decomposition products formed under fire conditions – Nature of decomposition products not known

Hazardous Polymerization

Will not occur

Reactivity

No information identified

Chemical stability

Stable when stored as recommended

Possibility of hazardous reaction

Not expected to occur

Conditions to avoid

No information identified

Incompatible material

No dangerous reaction known under conditions of normal

Hazardous decomposition products\

No information identified

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

No acute toxicities known

Irritation and Corrosion

Possible eye irritant

Sensitization

No sensitizing effects known

Chronic Exposure

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC (International Agency for Research on Cancer)

Signs and Symptoms of Exposure

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated

Potential Health Effects

Skin	May cause skin irritation. May be harmful if absorbed through skin
Eye	Causes eye irritation
Inhalation	May cause respiratory tract irritation. May be harmful if inhaled
Ingestion	May be harmful if swallowed
Human health data	See "Section 3 - Other Hazards"
Additional information	the toxicological properties of this mixture have not been fully characterized

12. ECOLOGICAL INFORMATION

Elimination Information (Persistence and Degradability) – Inherently biodegradable

Ecotoxicity Effects – No data available

Further Information on Ecology – No further information available

13. DISPOSAL CONSIDERATIONS

Substance Disposal

Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

Dispose of broken vials/syringes in a sharp container

14. TRANSPORT INFORMATION

RID / ADR – Non-hazardous for road transport

IMDG – Non-hazardous for sea transport

IATA – Non-hazardous for air transport

Environmental Hazards - Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant

Special precautions for User - Avoid release to the environment

15. REGULATORY INFORMATION

Labelling according to EC Directives

<u>Hazard Symbols</u>	<u>Meaning</u>
R-phrases)	No information available.
S-phrases)	No information available.

16. OTHER INFORMATION

Disclaimer: For R&D use only. Strictly not for drug or household uses

The above information is believed to be accurate to the best of our knowledge and shall be used strictly as a guide only. This shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. All materials and mixtures may present unknown hazards and should be used with caution. Veredus Laboratories Pte Ltd shall not be held liable for any damages or losses resulting from the handling or from contact with the above product

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