

SAFETY DATA SHEET



Truenat[®] MTB-RIF Dx

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Section 1: Identification of the substance /mixture and of the company undertaking

1.1 Product identifier

Product name: Truenat[®] MTB-RIF Dx

Product Reference number/Catalogue number : 5T : 601210005

20T: 601210020

25T: 601210025

50T: 601210050

100T: 601210100

200T: 601210200

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

Use of substance/mixture : Truenat[®] MTB-RIF Dx is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the detection of Rifampicin resistance in *Mycobacterium tuberculosis* (MTB) in Truenat[®] MTB/MTB Plus positive human specimen and aids in the diagnosis of MDR-TB. This test detects the presence of major mutations (SNPs) in the MTB genome that are known to cause resistance to rifampicin.

1.3 Details of the supplier of the safety data sheet

Company name: Molbio Diagnostics Private Limited.

Manufacturing :Site I
Plot No. L-46, Phase II D,
Verna Industrial Estate.
Verna, 403 722
Goa, INDIA.

Manufacturing : Site V
Plot No. L-42, Phase II B,
Verna Industrial Estate,
Verna, 403 722,
Goa , INDIA

www.molbiodiagnostics.com

Tel: +91 (0832) 2783267

Email: sales@molbiodiagnostics.com

1.4 Emergency telephone number

Emergency tel: +91 (0832) 2783267
(office hours only)

Section 2 : Hazards identification

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2.1 Classification of the substance or mixture

Classification under CLP: This product has no classification under CLP.

2.2 Label elements

Label elements: Not Applicable

Precautionary statements: Not Applicable

2.3 Other hazards

Not Applicable

Section 3 : Composition /information on ingredients

3.1 Substances

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The concentration of the raw material (chemicals) used in preparation of the Biomix is very negligible (< 0.1 % w/w) in the final buffer concentration. The product has no classification under CLP and is not falling under SVHC as per REACH Regulation (EC) No 1907/2006.

Contents:

Truenat[®] Blank chip PCBA (CAS number Not Applicable)

Biomix

Tricine (CAS # 5704-04-1)

Bovine Serum Albumin (CAS # 9048-46-8)

Potassium Chloride (CAS # 7447-40-7)

Tween 20 (CAS # 90005-64-5)

Trehalose (CAS # 6138-23-4)

Trizma HCl (CAS # 1185-53-1)

Magnesium Chloride (7786-30-3)

EDTA (CAS # 60-00-4)

Paraffin Wax (CAS # 8002-74-2)

Glycerol (CAS # 56-81-5)

Taq Polymerase (CAS number Not Applicable)

Primer- Probe mix (CAS number Not Applicable)

DNTPs (CAS number Not Applicable)

Uracil N Glycosylase(CAS number Not Applicable)

Section 4 : First aid measures

4.1 Description of first aid measures

Skin contact: Wash immediately with plenty of soap and water

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and if easy to do so. Continue rinsing. If eye irritation persists, seek medical advice/attention.

Ingestion: Solid material is not acutely toxic; however, if molten material is swallowed, seek immediate medical attention.

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Inhalation: Irritation is unlikely to occur but can be due to molten wax fumes, but in the event of discomfort, move the victim away from source of exposure and into fresh air, if necessary seek medical assistance.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact: Molten wax can cause thermal burns.

Eye contact: Redness and irritation.

Ingestion: There may be throat irritation.

Inhalation: No symptoms due to solid wax, but fumes might cause irritation and discomfort.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: If eye irritation persists, seek medical advice/ attention. If molten material is swallowed, seek immediate medical attention.

Section 5: Fire -fighting measures

5.1 Extinguishing media

Extinguishing media: Carbon dioxide, dry chemical powder or polymer foam.

5.2 Special hazards arising from the substance or mixture

Exposure hazards: No known specific hazards

5.3 Advice for fire fighters

Advice for fire-fighters: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Refer to section 8 of SDS for personal protection details.

6.2 Environmental precautions

Environmental precautions: Do not discard into drains or rivers, waste bins.

6.3 Methods and material for containment and cleaning up

Containment and Clean-up procedures: Spills of potentially infectious material should be cleaned up immediately with absorbent paper tissue and the contaminated area should be decontaminated with disinfectant such as 0.5% freshly prepared sodium hypochlorite.

Used Truenat[®] MTB-RIF Dx chip, remains of samples, reagents of human and animal origin, as well as contamination materials, disposables, neutralized acids and other waste materials must be discarded according to the local regulations after decontamination by immersion in a freshly prepared 0.5% of sodium hypochlorite for 30 minutes (1 volume if 5% sodium hypochlorite for 10 volumes of contaminated fluid or water)

6.4 Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage

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7.1 Precautions for safe handling

Handling requirements: No special requirements.

7.2 Conditions for safe storage , including any incompatibilities

Storage conditions: Store in original container between 2°C to 30°C. Do not expose to moisture and direct sunlight.

Suitable packaging: Must only be kept in original packaging.

7.3 Specific end use(s)

Specific end use(s): *In-vitro* diagnosis of *Mycobacterium tuberculosis*.

Section 8: Exposure controls/personal protection

8.1 Control parameters

Workplace exposure limits: No data available.

8.2 Exposure controls

Engineering measures: Ensure all engineering measures mentioned in section 7 of SDS are in place.

Respiratory protection: Respiratory protection not required.

Hand protection: Protective gloves.

Eye protection: No specific measures are required when using good safe practice.

Skin protection: Protective clothing not required when using good safe practice.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

State: Solid

Colour: White

Odour: Odourless

Solubility in water: Insoluble

Viscosity: Not Applicable

Boiling point/range°C: No data available

Flash point°C: No data available

Vapour pressure: No data available.

pH: Not Applicable

Melting point/range°C: No data available.

Autoflammability°C: No data available.

Relative density: No data available.

9.2 Other Information

Other information: None

Section 10: Stability and reactivity

10.1 Reactivity

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Reactivity: Stable under recommended transport or storage conditions.

10.2 Chemical stability

Chemical stability: Stable under specified conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions: No possible hazardous reactions.

10.4 Conditions to avoid

Conditions to avoid: Exposure to high temperature.

10.5 Incompatible materials

Materials to avoid: Organic solvents.

10.6 Hazardous decomposition products

Hazardous decomposition products: No hazardous decomposition products are formed in high quantities

Section 11: Toxicological information

Section 11.1 Information on Toxicological effects

Toxicity values: No data available.

Symptoms/routes of exposure

Skin contact: There may be mild irritation at the site of contact

Eye contact: There may be irritation and redness.

Ingestion: There may be irritation of the throat.

Inhalation: No symptoms due to solid wax, but fumes might cause irritation and discomfort.

Section 12: Ecological information

12.1 Toxicity

Ecotoxicity values: No data available.

12.2 Persistence and degradability

Persistence and degradability: Non-biodegradable.

12.3 Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4 Mobility in soil

Mobility: Not readily absorbed into soil.

12.5 Results of PBT and vPvB assessment.

Results of PBT and vPvB assessment: Not Applicable

12.6 Other adverse effects

Other adverse effects: Not Applicable

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Section 13: Disposal considerations

13.1 Waste treatment methods

Disposal operations: Dispose off in accordance with current legislation and local authority regulations as per established safety procedures. If outside the U.K, comply with local waste disposal regulations.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

14.1 UN number

UN number: Not Applicable

14.2 UN proper shipping name

Shipping name: This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.3 Transport hazard class(es)

Not Applicable

14.4 Packing group

Not Applicable

14.5 Environmental hazards

Environmentally hazardous: No potential hazard.

Marine pollutant: Not known

14.6 Special precautions for user

Special precautions: No special precautions.

Section 15: Regulatory information

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

Specific regulations: Not applicable.

15.2 Chemical Safety assessment

Chemical safety assessment: Not applicable.

Section 16: Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.