

# SAFETY DATA SHEET



## Truenat<sup>®</sup> GBS

Page 1 of 6

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

#### 1.1 Product identifier

**Product name:** Truenat<sup>®</sup> GBS

**Product Reference number/Catalogue number :** 5T : 601240005

20T: 601240020

25T: 601240025

50T: 601240050

100T: 601240100

200T: 601240200

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

**Use of substance/mixture :** Truenat<sup>®</sup> GBS is a chip based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection and diagnosis of group B streptococcus in vagino-rectal swabs, cerebrospinal fluid (CSF) and Blood/Serum/Plasma specimen and aids in the diagnosis of infection with group B streptococcus..

#### 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](http://www.molbiodiagnostics.com)

**Tel:** +91 (0832) 2783267

**Email:** [sales@molbiodiagnostics.com](mailto:sales@molbiodiagnostics.com)

#### 1.4 Emergency telephone number

**Emergency tel:** +91 (0832) 2783267

(office hours only)

### Section 2 : Hazards identification

# SAFETY DATA SHEET



## Truenat<sup>®</sup> GBS

Page 2 of 6

### 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

#### Truenat<sup>®</sup> GBS

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<sup>®</sup> 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.

**Inhalation:** Irritation is unlikely to occur but can be due to molten wax fumes, but in the event of discomfort, move the victim

# SAFETY DATA SHEET



## Truenat<sup>®</sup> GBS

Page 3 of 6

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<sup>®</sup> GBS 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

# SAFETY DATA SHEET



## Truenat<sup>®</sup> GBS

Page 4 of 6

### 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 group B streptococcus.

## 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

**Reactivity:** Stable under recommended transport or storage conditions.

# SAFETY DATA SHEET



## Truenat<sup>®</sup> GBS

Page 5 of 6

### 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

# SAFETY DATA SHEET



## Truenat<sup>®</sup> GBS

Page 6 of 6

### 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.