

SAFETY DATA SHEET

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

1.2 Product Identifier

Product Name : Lyse Vet
Catalog Number : 1126260500

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

Use of substance/mixture : Lyse is used by the hematological analyzer red blood cell hemolysing reagent for the assay of haemoglobin, white blood cell count, lymphocytes count, mid cell , granulocyte count.

1.3 Details of the supplier of the safety data sheet

Company Name : Coral Clinical Systems
(A Division of Tulip Diagnostics (P) Ltd.)
Tel : 91-832-6680121
Fax : 91-832-2887028
Email : coral@tulipgroup.com

1.4 Emergency Number

Emergency tel: +91-832-6624572 / +91-832-6680181

Section 2 Hazards Identification

2.1 Classification of the substance or mixture

Classification under CLP: This product has no classification under CLP.
The product is regulated as an in vitro diagnostic medical device and is not considered hazardous in accordance with regulation (EC) No.1272/2008.

2.2 Classification of the substance or mixture

Label elements : H317 (May cause an allergic skin reaction common due to preservative like CMIT).
Precautionary statements: Store at 23 to 29°C. Keep container tightly closed .
Dispose off waste in accordance to local guidelines.

2.3 Other Hazard

PBT: This product is not identified as a PBT/VPVB Substance.

Section 3 : Composition/ Information on Hazardous Ingredients

Coral Clinical Systems

A Division Of Tulip Diagnostics (P) Ltd.

Building E, Plot No. M-46/47, Phase IIIB, Verna Industrial Estate, Verna, Goa.

Section 3.1 Substances

Chemical Identity: In Vitro Diagnostic test. Used by the hematological analyzer red blood cell hemolysing reagent for the assay of haemoglobin, white blood cell count, lymphocytes count, mid cell , granulocyte count.

Contains: Contains no hazardous substances in reportable quantities under the CLP.

Section 4 : First aid measures

4.1 Description of first aid measures

Inhalation : Move the exposed person to fresh air. Keep at rest in a position comfortable for breathing. If breathing becomes difficult. Seek medical attention immediately.

Ingestion : Rinse mouth thoroughly with water. Get medical attention immediately.

Skin Contact : Remove contaminated clothing. Wash affected skin thoroughly with water. Get medical attention immediately.

Eye Contact : Immediately flush eyes with plenty of clean water for atleast 15 minutes. Seek prompt medical attention if irritation or redness persist.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact : May cause irritation on prolonged or repeated contact. Sensitized individuals may develop allergic dermatitis due to the presence of CMIT.

Eye contact : There may be irritation and redness.

Ingestion : There may be irritation of the throat. (Nausea, Abdominal discomfort and vomiting).

Inhalation: Inhalation of mist or vapour may cause irritation of the nose, throat and respiratory tract.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment : Not applicable

Section 5 : Fire Fighting Measures

5.1 Extinguishing Media

Product is non flammable, with a low risk of fire due to the flammability characteristics of the product in normal condition of storage, handling and use. In case of the existence of sustain combustion as a result of improper handling, storage any type of extinguishing agent can be used (ABC powder , water)

5.2 Special hazard arising from the substance or mixture

Exposure Hazard : Inhalation decomposition vapour or combustion product may cause respiratory irritation or shortness of breathe.

Fire fighter exposed to fumes should wear self-contained breathing apparatus and full

protective gear.

5.3 Advice for fire fighters

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self contained breathing apparatus. Do not enter fire without proper protective equipment, including respiratory protection.

Section 6 : Accidental Release Measures

Section 6.1 Personal precautions, protective equipment and emergency procedures

1. Refer to section 8 of SDS for personal protection details.
2. Turn leaking containers leak side up prevent the escape of liquid.

6.2 Environmental precautions

This product is not classified as hazardous to the environment. Keep product away from drain and ground water.

6.3 Methods and materials for containment and cleaning up

Clean-up procedures : For small spills, clean up with paper/cloth or mop up and dispose off safely. Clean area of spillage down with plenty of water.

6.4 Reference to other sections

Refer to section 8 of SDS

Section 7 Handling and Storage

7.1 Precautions and safe handling

Do not reuse the reagent containers, bottles, caps or plugs due to the risks of contamination and the potential to compromise reagent performance. Appropriate biosafety practices should be used for materials contain or are suspected of containing infectious agents. Handle specimens, solid and liquid waste and test components in accordance with local regulations.

7.2 Conditions for safe storage , including any incompatibilities

Storage condition: Store in original container at 23 to 29°C. Keep the container tightly closed and once opened must be closed back and kept in upright position to prevent leakage.

Suitable packaging: Must only be kept in original packaging.

7.3 Specific end use(s)

Specific end use(s) : Refer Section 1.2

Section 8 Exposure Controls and Personal Protection

8.1 Control parameters

Workplace exposure limits: Contains no substance with occupational exposure limit values.

DNEL/PNEC Values

DNEL/PNEC : No data available

8.2 Exposure Controls

Engineering measures : A system of local / general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source.

Respiratory Protection : Respiratory Protection is not required under normal use of this product. If respiratory is needed, follow OSHA respirator regulations (29CFR1910.134) And, if necessary, wear a NIOSH approved respirator. Select respirator based on its suitability to provide worker protection for given working conditions, level of airborne, concentration and presence of sufficient oxygen.

Eye and Skin Protection: Wear appropriate eye protection to prevent eye contact. Wear appropriate body protection to prevent skin contact.

Hand Protection : Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Other Engineering Controls : Eye wash stations and deluge showers

Section 9 : Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Lyse

State	: Liquid	Evaporating rate(nBuAc = 1)	: NA
Colour	: Colourless solution	Freezing / Melting Point	: NA
Odour	: Mild soapy	Boiling Point	: NA
Relative Vapour density(air = 1)	: NA	pH	: NA
Specific Gravity (water = 1)	: NA	Vapour Pressure, mm Hg @ 20°C	: NA
Solubility in Water	: Soluble	Viscosity	: NA

Section 9 : Other Information

Other Information : No data available

Section 10 : Stability and Reactivity

Coral Clinical Systems

A Division Of Tulip Diagnostics (P) Ltd.

Building E, Plot No. M-46/47, Phase IIIB, Verna Industrial Estate, Verna, Goa.

10.1 Reactivity

No hazardous reactions are expected because the product is stable under recommended storage condition.

10.2 Chemical Stability

- Chemically stable under indicated conditions of storage.
- Do not use if the container is damaged, contaminated or exceeded shelf-life.

10.3 Possibilities of hazardous reactions

Under the specified conditions, hazardous reactions that lead to excessive temperature or pressures are not expected.

10.4 Conditions to avoid

- Heat, direct sunlight, freezing and incompatible materials.
- Avoid contamination which may compromise stability.

10.5 Incompatible materials

Materials to avoid: Avoid strong acids strong bases

10.6 Hazardous Decomposition Products

Under expected conditions of use no hazardous decomposition product are known.

Section 11 : Toxicological information

11.1 Information on Toxicological effects

Toxicity Values : No data available

11.2 Symptoms/routes of exposure

- Eyes (redness)
- Skin (redness)
- Central nervous system (nausea/ vomiting)
- Cardiovascular systems (Hypotension and heart rate variability)
- Digestive systems (nausea/ vomiting/ diarrhea)

Section 12 : Ecological Information

12.1 Toxicity

Ecotoxicity values: No data available

12.2 Persistence and degradability

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The surfactant and Organic acids are expected to be biodegradable.

12.3 Bioaccumulation Potential

No data available

12.4 Mobility in soil

Water soluble; may spread in aquatic environment if released.

12.5 Results of PBT and vPvB assessment

PBT identification : This product is not identified as a PBT/vPvB substance.

12.5 Other adverse effects

Negligible ecotoxicity

Section 13 : Disposal Consideration

13.1 Waste treatment methods

Disposal operation: Dispose off in accordance with current legislation and local authority regulations as per established safety procedures.

Section 14 : Transportation Information

14.1 UN Number

N/A

14.2 Proper shipping name

N/A

14.3 Transport Hazard Class

N/A

14.4 Packing group

N/A

14.5 Environmental Hazard

Environmentally Hazardous: This product may be harmful to aquatic life with long-lasting effects due to the presence of cationic surfactants (e.g.Dodecyl Trimethyl Ammonium Chloride/Bromide) and sodium lauryl sulfate.

Marine pollutant : NA.

14.6 Special precautions for user

Precautions: Avoid release to the environment. Collect spillage. Dispose off content/ container in accordance with local regulation.

Section 15 : Regulatory Information

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

Specific regulation: Applicable national/regional or local regulations.
Safe for all kinds of modes of transportation.

15.2 Chemical safety assessment

This product is intended for in-vitro diagnostic use only. It contains small amounts of substances that may cause skin and eye irritation.

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.