SAFETY DATA SHEET

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

1.2 Product Identifier

Product Name : QUADRAPED™ SGPT (ALAT) Kit (Mod. IFCC Method)
Catalog Number : 1126190025

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

Use of substance/mixture : QUADRAPED™ SGPT (ALAT) Kit (Mod. IFCC Method) is used for the determination of SGPT (ALAT) in serum.

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 : H315 (Causes skin irritation)
H319 (Causes eye irritation)
Precautionary statements: Store at 2 to 8˚ 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

Section 3.1 Substances

Chemical Identity: In Vitro Diagnostic test for the determination of SGPT (ALAT) in serum.
Contains: Contains no hazardous substances in reportable quantities under the CLP.

Section 4 : First aid measures

4.1 Description of first aid measures

Inhalation : If breathing becomes difficult, remove victim to fresh air. Seek medical attention immediately.

Ingestion : Get medical attention if there has been ingestion of this product.

Skin Contact : Avoid skin contact. If skin contact occurs, remove contaminated clothing and wash exposed skin with water for atleast 15 minutes. Get medical attention immediately.

Eye Contact : Immediately flush eye(s) with large volume of water for atleast 15 minutes, occasionally lifting the lower lids. Get medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

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

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

Extinguishing Media : Suitable extinguishing media such as carbon dioxide, dry chemical powder or polymer foam for the surrounding fire should be used.

5.2 Special hazard arising from the substance or mixture

Exposure Hazard : No known specific hazards.
Structural fire fighting gear and self contained breathing apparatus will provide adequate protection if this product is in a fire area.

5.3 Advice for fire fighters

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

Drains & Water ways : Keep the product away from drains, surface water and ground water.
Spill handling : For large spill mechanically collect with adsorbants, do not wash into drains.
Disposal : Use closed containers; follow local hazardous-waste regulations.

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 between 2˚C to 8˚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

L1 - Enzyme Reagent

State	: Liquid	Evaporating rate(nBuAc = 1)	: NA
Colour	: Colourless	Freezing / Melting Point	: NA
Odour	: Odourless	Boiling Point	: NA
Relative Vapour density(air = 1)	: NA	pH	: 7.4± 0.05
Specific Gravity (water = 1)	: NA	Vapour Pressure, mm Hg @ 20˚C	: NA
Solubility in Water	: Soluble	Viscosity	: NA

S - Starter Reagent

State	: Liquid	Evaporating rate(nBuAc = 1)	: NA
Colour	: Colourless	Freezing / Melting Point	: NA
Odour	: Odourless	Boiling Point	: NA
Relative Vapour density(air = 1)	: NA	pH	: 9.6-9.8
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

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.

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

Avoid freezing the reagent, protect from light and prevent contamination.

10.5 Incompatible materials

Materials to avoid: Strong bases (KOH), strong acids (HCL), water reactive materials (NaN_3), oxidizing agents and materials that could cause decomposition of reagent .

10.6 Hazardous Decomposition Products

Thermal decomposition may produce carbon monoxide and carbon dioxide

Section 11 : Toxicological information

11.1 Information on Toxicological effects

Toxicity Values : No data available

11.2 Symptoms/routes of exposure

- **Eyes :** redness
- **Skin :** Irritation /redness ; possible adsorption effect
- **Ingestion :** Stomach pain, nausea, vomiting
- **Inhalation :** Respiratory irritation (cough ,throat discomfort)

Section 12 : Ecological Information

12.1 Toxicity

Ecotoxicity values: No data available

12.2 Persistance and degradability

No data available

12.3 Bioaccumulation Potential

No data available

12.4 Mobility in soil

No data available

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: Reagents in this kit contain Sodium Azide. Improper disposal of sodium azide, such as flushing it down the drain can lead to contamination of wastewater treatment systems .

Marine pollutant : NA

14.6 Special precautions for user

Precautions: SGPT (ALAT) contain sodium azide (NaN_3) as preservative. Sodium azide has been reported to form lead or copper azide in laboratory plumbing, which may explode on percussion. Flush drains with large volumes of water thoroughly after disposing off the fluids containing sodium azide.

Avoid cross contamination between reagents and samples.

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

The SGPT (ALAT) contain sodium azide (NaN_3) as preservative.

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 b 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.