

Annexure XIII

Safety Data Sheet

SAFETY DATA SHEET

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

1.2 Product Identifier

Product Name : QUADRAPED™ Albumin Kit (Bromocresol Green Method)
Catalog number: 1126010025

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

Use of substance/mixture : It is used for the determination of Albumin in serum or plasma.

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 Other Information

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 : None are Present

Precautionary statements: Store at 23 to 29° C. Keep container tightly closed and protect from contamination.

Note : Standard to be stored between 2 to 8° C.

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 Albumin.

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

6.1 Suitable Extinguishing Media

Suitable extinguishing media such as carbon dioxide, dry chemical powder or polymer foam.

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

Do not discharge into drains or rivers.

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 23°C to 29°C &. Keep the container tightly closed and once opened must be closed back and kept in upright position to prevent leakage.

Note : Standard to be stored between 2° C to 8° C

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

8.3 Work Practices

Good laboratory technique should be used when handling this product. Observe appropriate chemical hygiene. Avoid contact with eyes or skin. Do not place in mouth.

8.4 DNEL/PNEC

No data available

Section 9 : Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

L1 - BCG Reagent

State	: Liquid	Evaporating rate(nBuAc = 1)	: NA
Colour	:Greenish to golden yellow	Freezing / Melting Point	: NA
Odour	: Odourless	Boiling Point	: NA
Relative Vapour density(air = 1)	: NA	pH	: 3.8 - 4.2
Specific Gravity (water = 1)	: NA	Vapour Pressure, mm Hg @ 20°C	: NA
Solubility in Water	: Soluble	Viscosity	: NA

S - Albumin Standard

State	: Liquid	Evaporating rate(nBuAc = 1)	: NA
Colour	: colorless	Freezing / Melting Point	: NA
Odour	: Odourless	Boiling Point	: NA

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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

10.1 Reactivity

Stable under recommended transport or storage conditions

10.2 Chemical Stability

Stable under normal handling and storage conditions

10.3 Possibilities of hazardous reactions

Hazardous reactions will not occur under normal transport or storage conditions.

10.4 Conditions to avoid

Avoid acidification of solution, which may generate hydrogen cyanide gas.

10.5 Incompatible materials

Materials to avoid: Strong bases, strong acids and water reactive materials.

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 (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

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.

12.6 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 Packing Group

N/A

14.4 Hazard Class

N/A

14.5 Environmental Hazard

Environmentally Hazardous: Reagents in this kit contain Sodium Azide.

Marine pollutant : Albumin (BCG) Kit contain reagent like Bromocresol Green (BCG), a dye that can be toxic to be aquatic organisms to high concentration.

14.6 Special precautions for user

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Precautions: Albumin (BCG) 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.

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

Albumin (BCG) 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 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.