



1. INFORMATION OF THE SUBSTANCE / PREPERATION AND COMPANY

1.1. Product name Brucellosis Positive Control

Catalogue No	Kit components
110200005, 110200001,110201000	Brucellosis Positive Control
	Package Insert

1.2. Intended use In Vitro Diagnostic Use.

1.3. Company Tulip Diagnostics (P) Ltd.
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Verna Industrial Estate,
Verna, Goa 403 722
INDIA
Telephone : +91-832-6624555
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1.4. In emergencies :Call your local emergency center.

2. HAZARDOUS IDENTIFICATION

- 2.1 Classification of the substances or mixture
Classification according to regulate (EC) No. 1272/2008
The Mixture is Classified non Hazardous according to regulation (EC) No. 1272/2008
- 2.2 Label Elements
Labelling according to Regulation (EC) No. 1272/2008
Hazard pictograph :None
Signal Word :None
Hazard statements :None
- 2.3 Other hazards
None

3. COMPOSITION / INFORMATION ON INGREDIENTS

Brucellosis positive control contains 0.1% Sodium Azide (cas No -26628-22-8)
(EC no-247-852-1).The Classification of Sodium Azide (100%) according to regulation (EC)
no.1272/2008 is Acute toxicity 2*, Aquatic acute 1 Aquatic chronic 1. H300,H400,H410.

4. FIRST AID MEASURES

- Eye contact* : - Rinse immediately with water. Do not apply neutralizing agents. Consult a doctor/medical service.
- Skin contact* :- Rinse with water.
 - Consult a doctor/medical service if irritation persists.
- After inhalation* :- Remove the victim into fresh air.
 - Unconscious: maintain adequate airway and respiration .



- Consult a doctor/medical service if breathing problems develop.

After swallowed -:- Wash out mouth with plenty of water, Drink plenty of water. Call a doctor or medical service.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:

- All non combustible extinguishing media allowed
- For surrounding fires: all extinguishing media allowed.

Unsuitable extinguishing media:

- No data available.

Special exposure hazards:

- On heating/burning: formation of small quantities of nitrous vapors, carbon monoxide, carbon dioxide

Instructions:

- Take account of toxic firefighting water.

Special protective equipment for firefighters:

- Use firefighting water moderately and contain it
- Heat/fire exposure: compressed air/oxygen apparatus
- Heat/fire exposure: gas-tight suit

6. ACCIDENTAL RELEASE MEASURES

Personal protection: see 8

Environmental precautions:

- Prevent soil and water pollution
- Substance must not be discharged into the sewer
- Contain leaking substance, pump over in suitable containers
- Plug the leak, cut off the supply
- Dam up the liquid spill

Clean-up:

- Take up liquid spill into absorbent material
- Scoop absorbed substance into closing containers
- Carefully collect the spill/leftovers
- Clean contaminated surfaces with an excess of water
- Wash clothing and equipment after handling

7. HANDLING AND STORAGE

Handling:

- Observe normal hygiene standards
- Do not discharge the waste into the drain
- Remove and clean contaminated clothing

Storage:

- Provide for a tub to collect spills
- Meet the legal requirements
- Keep away from: heat sources, acids
- Storage temperature: see component label
- Keep tightly closed
- Keep away from heat, sparks and open flame.
- Store in a cool dry place.



Specific purposes:

- NA

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 Control parameters

Does not contain substances with exposure limit values.

8.2 Control of Exposure

8.1.1 Exposure to persons

Respiratory Protection

- Insufficient ventilation: wear respiratory protection

Hand Protection

- Gloves

Eye Protection

- Face shields

Skin Protection

- Protective Clothing

9. PHYSICAL AND CHEMICAL PROPERTIES

Brucellosis Positive Control : Clear Straw Colour Liquid.

10. STABILITY AND REACTIVITY

Stability: The component is stable until expiry date if stored in specified conditions (see label)

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

Conditions/Materials to avoid: Keep away from metals and acids (Component contains azide)

11. TOXICOLOGICAL INFORMARTION

Sodium Azide:

Toxicity and effects

Acute toxicity: LD50 oral rat : 27 mg/kg

LD50 dermal rabbit : 20 mg/kg

Acute effects: Harmful if swallowed

Chronic toxicity: Carcinogenicity (TLV) : A4

Routes of exposure

Ingestion, inhalation, eyes and skin

Caution! These components contain a substance that is absorbed through the skin (sodium azide).



12. ECOLOGICAL INFORMATION

Aquatic toxicity

- Sodium azide:*
- LC50 (96 h) : 0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUS MYKISS)
 - LC50 (96 h) : 0.7 mg/l (LEPOMIS MACROCHIRUS)
 - LC50 (48 h) : 9 mg/l (GAMMARUS SP.)

Other information

- Effect on the ozone layer: Not dangerous for the ozone layer
- Greenhouse effect: No data available
- Effect on waste water purification: No data available

13. WASTE DISPOSAL CONSIDERATIONS

Provisions relating to waste: Hazardous waste (91/689/EEC).

Packaging/container: Waste material code packaging (91/689/EEC, Council Decision 2001/118/EC, O.J. L47 of 16/2/2001): 15 01 10 (packaging containing residues of or contaminated by dangerous substances)

Disposal methods:

- The component must be considered as hazardous waste. It should be disposed of following local regulations.
- Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides.

14. TRANSPORT INFORMATION

No restrictions.

15. REGULATORY INFORMATION

No specific regulation.

16. OTHER INFORMATION

The following Hazard statements refer to the classification of the components (Pure Substances 100%) and not the classification of the mixture .

- H300 - fatal if swallowed .
- H400 - Very toxic to aquatic life.
- H410 - Very toxic to aquatic life with long lasting effects.
- EUH032 - Contact with acids liberates very toxic gas .

This product is designed for use by professionals.

The animal source material included in this lot are considered to be free for risk for BSE/CJD and other zoonoses and judged to be non-existent based on:

The materials used from animal origin are sources from NON – BSE countries (Certificate available). But handling of reagent serum or plasma specimens should be in accordance with local safety procedure.



SAFETY DATA SHEET

(According to CLP regulation (EC) No.1272/2008,

EC No 1907/2006 article 31)

Product: Brucellosis Positive Control

Doc. No. SDS/429

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

It remains the user's own responsibility to make sure that the information is appropriate and complete for his specific use of this product. The user is also responsible for observing any laws and applicable guidelines.

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