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SAFETY DATA SHEET (According to CLP regulation (EC) No 1272/2008 EC NO 1907/2006 article 31) Product : Brucel - A/Brucel - M/Brucel - RB Antigens Doc. No. SDS/426-428

### **1. INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY**

1.1. Product name Brucel - A /Brucel - M /Brucel - RB Antigens

Kit components			
	Catalogue No	Antigen Suspension	
	105610005,105611000	Brucella abortus	
	105620005,105621000	Brucella melitensis	
	105630005,105631000	Brucella Rose Bengal	

All pack sizes contain package insert

1.2.	Intended use	In Vitro Diagnostic Use.	
1.3.	Company	Tulip Diagnostics (P) Ltd. Plot No.Utility VIII, Phase III B,	
		Verna Industrial Estate,	
		Verna, Goa 403 722	
		INDIA	
		Telephone : +91-832-6624555	
		Fax : +91-832-2783511	
		E-mail : - <u>sales@tulipgroup.com</u>	
1.4.	In emergencies	Call your local emergency center.	

### 2. HAZARDOUS IDENTIFICATION

 Classification of the substances or mixture Classification according to regulate (EC) No.1272/2008 The mixture is classified as 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

Brucel Reagent contains 0.01% Thimerosal (cas No - 54-64-8) (EC No - 200-210 - 4) The classification of (0.01%) according to regulation (EC) no.1272/2008 is H317,H413.

### 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.

Compiled by Tulip Diagnostics (P) Ltd. Plot No. Utility VIII, Phase IIIB, Verna, Goa, India



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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:

Unsuitable extinguishing media: Special exposure hazards:

- All non combustible extinguishing media allowed
- For surrounding fires: all extinguishing media allowed
- No data available
- On heating/burning: formation of small quantities of nitrous vapors, carbon monoxide, carbon dioxide
- Take account of toxic firefighting water.
  - Use firefighting water moderately and contain it.

Special protective equipment for firefighters:- 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:

Instructions:

- 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

Specific purposes:

- NA



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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Does not contain substances with exposure limit values.

### 8.2 Control of Exposure

#### 8.2.1 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

Antigen suspensions	: Liquid
Odour	: Not specific
Odour threshold	: No data available
Conductivity	: 10-20mS/cm

# **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.

# **11. TOXICOLOGICAL INFORMATION**

### <u>Thimerosal</u>

Toxicity	and	effects
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Acute toxicity:	LD50 oral rat	: 75 mg/kg	
	LC50	: NE	
Acute effects:	Harmful if swallo	Harmful if swallowed	

### **Routes of exposure**

Ingestion, inhalation, eyes and skin

# **12. ECOLOGICAL INFORMATION**

### **Aquatic toxicity**

The ecological information for the dilute thimerosal has not been thoroughly investigated : however mercury and its compound are expected to significantly bioaccumulate . So any waste must be handled as dangerous waste

### **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



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### **13. WASTE DISPOSAL CONSIDERATION**

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

Packaging/container: Waste material code packaging (91/689/EEC, Council Decision<br/>2001/118/EC, O.J. L47 of 16/2/2001):15 01 10 (packaging<br/>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.

### **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 .

Labels - none required due to dilution .

H317 - May cause an allergic Skin reaction.

H413 - May cause long lasting harmful effects to aquatic life.

This product is designed for use by professionals.

The material from animal source included in this kit are considered and judged to be free from risk of BSE/CJD and other zoonoses based on :

The material used from animal origin are source from non-BSE countries (certificate available). But the handling of reagents, serum or plasma specimen should be in accordance with local safety procedure.

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.

**SDS established** : 2022-02-11 **Revision number** : 01