SAFETY DATA SHEET

indosera™ ABO Screen

Section 1. Information of the Product & Company

1. 1	Product Name	:	INDOSERA™ ABO Screen
	Brand Name	:	Indosera ™
1. 2	Catalogue No. (Ref.No)	:	6211070310
	Pack Size	:	10 ml / vial, 3 vials / box
	Kit Components	:	1 vial reagent Anti-A Monoclonal, 1 vial reagent Anti-B Monoclonal, 1 vial reagent Anti-AB Monoclonal, 1 pcs Packinsert
1. 3	Group / Risk Class	:	In Vitro Diagnostics / C Class
	Product Category	:	Hematology and Pathology Equipments
	Sub Category	:	Products used in the manufacture of blood preparations and preparations derived from blood
	Product Type	:	Blood group substances of nonhuman origin for in vitro diagnostic use.
1. 4	Company Name	:	PT TULIP DIAGNOSTICS INDONESIA Kawasan Industri Candi Blok H3, Purwoyoso, Ngaliyan, Semarang, Jawa Tengah - Indonesia (50184)
1. 5	Intended Use of Product	:	In Vitro Diagnostics use
1. 6	In Emergencies	:	(024) 7627321 / 7627323 or Call your local emergency center

Section 2. Hazards Identification

2. 1 Classification of the Substance or Mixture
Classification according to regulation (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 pictogram : None
Signal word : None
Hazard statements : None

2. 3 Other Hazards
None

Section 3. Information on Ingredients

indosera™ ABO Screen has Anti-A Monoclonal, Anti-B Monoclonal, Anti-AB Monoclonal blood grouping reagent that contain :
0.1 % Sodium Azide (cas no – 26628-22-8) (EC no- 247-852-1).
The classification of Sodium Azide according to regulation (EC) no.1272/2008 is Acute toxicity 2 * , Aquatic Acute 1 Aquatic Chronic 1.
H300, H400, H410

Section 4. First Aid Measures

4.1	Eye Contact	:	Rinse immediately with water. Do not apply neutralizing agents. Consult a doctor /medical service
4.2	Skin Contact	:	Rinse with water, Consult a doctor/medical service if irritation persists
4.3	After inhalation	:	Remove the victim into fresh air,Unconscious: maintain adequate airway and respiration. Consult a doctor/medical service if breathing problems develop
4.4	After Swallowed	:	Wash out your mouth with plenty of water. Drink plenty of water. Call a Doctor or medical service.

Section 5. Fire Fighting Measures

5.1	Suitable extinguishing media	:	- All non combustible extinguishing media allowed - For surrounding fires: all extinguishing media allowed
5.2	Unsuitable extinguishing media	:	No data available
5.3	Special exposure hazards	:	On heating/burning: formation of small quantities of nitrous vapors, carbon

Section 5. Fire Fighting Measures

monoxide, carbon dioxide

5.4 Instructions : - Take account of toxic firefighting water
- Use firefighting water moderately and contain it

5.5 Special protective equipment for firefighters : - Heat/fire exposure: compressed air/oxygen apparatus
- Heat/fire exposure: gas-tight suit

Section 6. Accidental Release Measures

6.1 Personal protection : See Section 8

6.2 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

6.3 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

Section 7. Handling and Storage

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

7.2 Storage :
- Provide for a tub to collect spills
- Meet the legal requirements
- Keep away from: heat sources, acids
- Storage temperature: see component label

7.3 Specific Purpose : N/A

Section 8. Exposure Control / Personal Protection

8.1 Control Parameters : Does not contain substances with exposure limit values.

8.2 Control of Exposure :
- Respiratory Protection : Insufficient ventilation: wear respiratory protection
- Hand Protection : Gloves
- Eye Protection : Face shields
- Skin Protection : Protective Clothing

Section 9. Physical & Chemical Properties

9.1 Reagent Appearance : Anti-A Monoclonal : Blue color liquid
Anti-B Monoclonal : Yellow color liquid
Anti-AB Monoclonal : Colorless clear Liquid

9.2 Odour : Not Specific

Odour threshold : No data Available

9.3 pH : 7.0 - 7.4

Section 10. Stability & Reactivity

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

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

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

Section 11. Toxicological Information

11.1 Toxicity and effects : Acute toxicity:
LD50 oral rat = 27 mg/kg
LD50 dermal rabbit = 20 mg/kg
Acute effects:
Harmful if swallowed

11.2 Routes of exposure : Ingestion, inhalation, eyes and skin
Caution! These components contain a substance that is absorbed through the skin (sodium azide).

Section 12. Ecological Information

12.1 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.)

12.2 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

Section 13. Waste Disposal Considerations

13. 1 Provisions relating to waste : Hazardous waste (91/689/EEC).

13. 2 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)

13. 3 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.

Section 14. Transport Information

No restrictions.

Section 15. Regulatory Information

No specific regulations

Section 16. Other Information

The following Hazard statements refer to the classification of the components (pure substance 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 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 use of BSA from sources in non-BSE countries (certificate available). But the handling of reagent, serum or plasma specimens should be in accordance with local safety procedures.

Section 16. Other Information

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.