



## SAFETY DATA SHEET

indonella™ 4.0

Version 02  
Release Date 04.06.2025  
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### Section 1. Information of the Product & Company

- 1.1 Product Name : indonella™ 4.0  
Brand Name : indonella™
- 1.2 Catalogue No. (Ref.No) : 6214010405  
Pack Size : 4 reagents @ 5 ml, 1 reagent 4.0 ml  
Kit Components :
  - 5 ml reagent Widal antigen S. typhi 'O'
  - 5 ml reagent Widal antigen S. typhi 'H'
  - 5 ml reagent Widal antigen S. paratyphi 'AH'
  - 5 ml reagent Widal antigen S. paratyphi 'BH'
  - 0.4 ml reagent Widal Positive Control
  - 1 pcs Glass slide contains 6 circles
  - 2 x 25 pcs Mixing rod
  - 50 pcs Blue PP tubes
  - 1 pcs Paper fitment with 5 holes
  - 1 pcs indonella™ 4.0 Pack insert
- 1.3 Group / Risk Class : In Vitro Diagnostics / B Class  
Product Category : Immunology & Microbiology Equipments  
Sub Category : Serological Reagents  
Product Type : Salmonella spp. Serological reagents.
- 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 : Reagents that are used to detect the presence of the serum agglutinins (O,H,AH,BH) in the human serum specimens that have fever.
- 1.6 In Emergencies : Call (024) 7627321 / (024) 7627323 (office hours only) or Call your local emergency center

### Section 2. Hazards Identification

- 2.1 Classification of the Substance or Mixture  
Classification under CLP : This product has no classification under CLP.  
Classification according to regulation (EC) : 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 Label Elements  
Hazard pictogram : None  
Signal word : None  
Hazard statements : None
- 2.3 Other Label  
Ⓟ symbol (white P letter inside the black circle) : Professional use only
- 2.4 Other Hazards  
This product is not identified as a PBT/vPvB substance.

### Section 3. Information on Ingredients

Product of indonella™ 4.0 for each packaging contains :

5 ml reagent Widal antigen S. typhi 'O' ; 5 ml reagent Widal antigen S. typhi 'H' ; 5 ml reagent Widal antigen S. paratyphi 'AH' ; 5 ml reagent Widal antigen S. paratyphi 'BH' ; 0.4 ml reagent Widal Positive Control ; 1 pcs Glass slide contains 6 circles ; 2 x 25 pcs Mixing rod ; 50 pcs Blue PP tubes ; 1 pcs Paper fitment with 5 holes ; 1 pcs indonella™ 4.0 Pack insert

Each Indonella 4.0 reagent contains 0.1% Sodium Azide ( cas No -26628-22-8) (EC no-247-852-1).

The Classification of Sodium Azide (100% pure) according to regulation (EC)no. 1272/2008 is Acute toxicity 2\*, Aquatic acute 1 Aquatic chronic 1. H300,H400,H410.



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### Section 4. First Aid Measures

- 4.1 Eye Contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. If eye irritation persists, Consult a doctor /medical service.
- 4.2 Skin Contact : Wash immediately with plenty of soap and water.
- 4.3 After inhalation : Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary seek medical assistance.
- 4.4 After Swallowed : Do not induce vomiting. Wash your mouth with water and give plenty of water or milk to drink immediately. Obtain medical attention if necessary and show a label on the container.

Symptoms / routes of exposure :

- 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.

Immediate / Special treatment : Not applicable.

### Section 5. Fire Fighting Measures

- 5.1 Suitable extinguishing media : Suitable extinguishing media such as carbon dioxide, dry chemical powder or polymer foam for the surrounding fire should be used. For surrounding fires: all extinguishing media allowed  
Use water spray to cool containers.
- 5.2 Unsuitable extinguishing media : No data available
- 5.3 Special exposure hazards : No known specific hazards
- 5.4 Instructions :
  - Take account of toxic firefighting water
  - Use firefighting water moderately and contain it
- 5.5 Advice for firefighters :
  - Heat/fire exposure: compressed air/oxygen apparatus
  - Personnel : Do not enter fire without proper protective equipment, including respiratory protection.

### Section 6. Accidental Release Measures

- 6.1 Personal protection :
  - Follow Standard Biosafety guidelines during handling of potentially infectious human specimens.
  - Refer to section 8 of SDS for personal protection details.
  - Turn leaking containers leak-side up to prevent the escape of liquid.
- 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
- 6.4 Reference to other sections : Refer to section 8 of SDS.

### Section 7. Handling and Storage

- 7.1 Handling Requirements :
  - Refer to Pack insert indonella™ 4.0
  - Observe normal hygiene standards
  - Do not discharge the waste into the drain
  - Remove and clean contaminated clothing



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## Section 7. Handling and Storage

- 7.2 Storage conditions : Store in the original container at a temperature 2-8°C. Keep the reagents container tightly closed and once opened must be carefully closed back and kept in an upright position to prevent leakage.
- 7.3 Specific Purpose : Refer to pack insert for indonella™ 4.0
- 7.4 Suitable Packaging : kept in original packaging.
- 7.5 Specific end use(s) : Refer to Section 12.

## Section 8. Exposure Control / Personal Protection

- 8.1 Control Parameters : Does not contain substances with exposure limit values.
- 8.2 Control of Exposure :
  - Engineering measures : Ensure all engineering measures mentioned in section 7 of SDS are in place.
  - Respiratory Protection : Insufficient ventilation: wear respiratory protection
  - Hand Protection : Protective gloves.
  - Eye Protection : No specific measures are required when using good safe practice.
  - Skin Protection : Protective clothing not required in normal use. Use proper glove removal technique to avoid skin contact.

## Section 9. Physical & Chemical Properties

		Reagents
a	State	Liquid (all reagents & positive control)
b	Odour	Odourless
c	Threshold	No data available
d	Conductivity	10-20 mS/cm

## Section 10. Stability & Reactivity

- 10.1 Stability : The component is stable until expiry date if stored in specified conditions (see IFU)
- 10.2 Reactivity/Hazardous reaction : Stable under normal conditions. Hazardous reactions will not occur under normal transport or storage conditions.
- 10.3 Conditions/Materials to avoid : Heat and moisture and direct sunlight.
- 10.4 Hazardous decomposition products : Carbon monoxide, Carbon dioxide.
- 10.5 Materials to avoid : Strong oxidizing agents
- 10.6 Incompatible with : aniline, phenol, isocyanates, anhydrides, strong acids, strong bases, amines, peroxides, acid chlorides, acid anhydrides, alkali metals, reducing agents.

## Section 11. Toxicological Information

- 11.1 Toxicity values : Sodium Azide  
Acute toxicity: LD50 oral rat : 27 mg/kg , LD50 dermal rabbit : 20 mg/kg  
Acute effects: Harmful if swallowed  
Formaldehyde  
Acute toxicity: Inhalation may result in spasm, inflammation and edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema. Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea and vomiting. Material is extremely destructive to tissue of the mucous membranes and upper respiratory tract, eyes and skin. Exposure can cause: coughing, chest pains, difficulty in breathing. Gastrointestinal disturbances. May cause convulsions. To the best of our



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### Section 11. Toxicological Information

knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Chronic toxicity:

Carcinogenicity (TLV): A4

This product is or contains a component that has been reported to be possibly carcinogenic based on its IARC, ACGIH, NTP or EPA classification. May alter genetic material. Carcinogen Category 3

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 Ecotoxicity : Sodium azide:  
LC50 (96 h) : 0.8 mg/l (SALMO GAIRDNERI/ONCORHYNCHUSMYKISS)  
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  
Formaldehyde : BOD 5: 60%  
Effect on waste water purification: No data available

### Section 13. Waste Disposal Considerations

13.1 Disposal operations : Disposal of chemical, hazardous or laboratory wastes / waste product and / or packaging must be carried out in accordance with all applicable local/regional official regulations.  
Uncleaned packaging should be disposed of in accordance. Water if necessary together with appropriate cleansing agents may be used for decontamination before disposal.

Note : The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.  
Sodium Azide reacts with lead and copper plumbing forming highly explosive metal Azides.

### Section 14. Transport Information

Special precautions: 1. Shipper boxes should be arranged / stacked in the direction as indicated by the shipper label / Carton.  
2. Avoid over-stacking. Do not stack more than 5 boxes.  
3. The reagent in this clearing buffer contains Sodium Azide as a 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 of fluids containing Sodium Azide.

### Section 15. Regulatory Information

Chemical Safety Assessment : The Clearing buffer contains 0.1% of Sodium Azide (NaN<sub>3</sub>) as preservative. CAS:No.: 26628-228  
EINECS-No.: 247-852-1

### Section 16. Other Information

This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

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.

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**Section 16. Other Information**

This product is designed for use by professionals.

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.