



# Safety Data Sheet (SDS)

According to Regulation (EC) No 453/2010

## Panbio Dengue IgM Capture ELISA

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Version : 0

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

Trade name/designation : Panbio Dengue IgM Capture ELISA(Wash buffer, Sample diluent, Antigen Diluent Buffer, Dengue 1-4 Antigen, HRP conjugate)

Cat. No. : 01PE20, 01PE21

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

##### 1.2.1. Relevant identified uses

- Not available

##### 1.2.2. Uses advised against

- Not available

#### 1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier : Standard Diagnostics, Inc.

Address : 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea

Telephone : 82 (31) 899-2861

Email : yrhan@standardia.com

#### 1.4. Emergency telephone number

Telephone number : 82 (31) 899-2882

### SECTION 2: HAZARD IDENTIFICATION

#### 2.1. Classification of the substance/mixture

##### 2.1.1. Classification according to Regulation (EC) No 1272/2008 [CLP]

- Skin corrosion/irritation : Category2, H315
- Serious eye damage/irritation : Category2, H319
- Skin sensitization : Category1, H317

#### 2.2. Label elements

##### 2.2.1. Labelling according to Regulation (EC) No 1272/2008 [CLP]

###### \* Hazard Pictogram(s)



\* Signal word : Warning

###### \* Hazard statement(s)

- H315 Causes skin irritation
- H317 May cause an allergic skin reaction
- H319 Causes serious eye irritation

###### \* Precautionary statement(s)

###### 1) Prevention

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P264 Wash hands thoroughly after handling.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

**2) Response**

- P302+P352 IF ON SKIN: Wash with plenty of soap and water.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P321 Specific treatment
- P332+P313 If skin irritation occurs: Get medical advice/attention.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P362 Take off contaminated clothing and wash before reuse.
- P363 Wash contaminated clothing before reuse.

**3) Storage**

- Not applicable

**4) Disposal**

- P501 Dispose of contents/container in accordance with local/regional/national/international regulation

**2.3. Other hazards**

- Not available

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS****3.1. Substances**

- Not applicable

**3.2. Mixtures**

Product Description	Ingredient Name	% [weight]
Wash Buffer	(*) Proclin 300	≤0.1
TMB Chromogen	Tetramethylbenzidine	≤100
Stop Solution	Ortho-phosphoric acid	≤7
Sample Diluent	(*) Proclin 300	≤0.1
Antigen Diluent Buffer	Gentamicin Sulphate	≤0.5
	(*) Proclin 300	≤0.1
Dengue 1-4 Antigen	Gentamicin Sulphate	≤0.2
	(*) Proclin 300	≤0.04
Dengue IgM Capture MAb Tracer HRP	(*) Proclin 300	≤0.1
Dengue IgM Capture Control	Gentamicin Sulphate	≤0.005
	Sodium azide	≤0.1

(\*) Proclin 300 = reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)

Chemical	CAS No.	Classification [1272/2008/EC]
(*) reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)	55965-84-9	Skin Irrit. 2; H315, Eye Irrit. 2; H319, Skin Sens. 1; H317
Tetramethylbenzidine	54827-17-7	Not classified
Ortho-phosphoric acid	7664-38-2	The product does not contain reportable quantities of dangerous components.
Gentamicin Sulphate	1405-41-0	Not classified
Sodium azide	26628-22-8	The product does not contain reportable quantities of dangerous components.

**SECTION 4: FIRST AID MEASURES****4.1. Description of first aid measures****General**

- No general information.

**Inhalation**

- When exposed to large amounts of steam and mist, move to fresh air.
- Take specific treatment if needed.

**Skin**

- Flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

- Laundering enough contaminated clothing before reuse.
- Go to the hospital immediately if symptoms (flare, irritate) occur.
- Wash thoroughly after handling.

#### **Eye**

- Do not rub your eyes.
- Immediately flush eyes with plenty of water for at least 15 minutes and call a doctor/physician.
- Go to the hospital immediately if symptoms (flare, irritate) occur.
- Remove contact lenses if worn.

#### **Ingestion**

- About whether I should induce vomiting Take the advice of a doctor.
- Rinse your mouth with water immediately.

### **4.2. Most important symptoms and effects, both acute and delayed**

- Not available

### **4.3. Indication of any immediate medical attention and special treatment needed**

- Notify medical personnel of contaminated situations and have them take appropriate protective measures.

## **SECTION 5: FIREFIGHTING MEASURES**

### **5.1. Extinguishing media**

#### **Suitable extinguishing media**

- Dry chemical, carbon dioxide, regular foam extinguishing agent, spray

#### **Unsuitable extinguishing media**

- Avoid use of water jet for extinguishing

### **5.2. Special hazards arising from the substance or mixture**

#### **Hazardous combustion products**

- Not available

### **5.3. Advice for firefighters**

- Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank.
- Using a unattended and water devices in case of large fire and leave alone to burn if you do not imperative.
- Avoid inhalation of materials or combustion by-products.
- Do not access if the tank on fire.
- Use appropriate extinguishing measure suitable for surrounding fire.
- Keep containers cool with water spray.
- Use fire fighting procedures suitable for surrounding area.
- Vapor or gas is burned at distant ignition sources can be spread quickly.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

### **6.1. Personal Precautions, protective equipment and emergency procedures**

#### **6.1.1. For non-emergency personnel**

- Protective equipment: Wear proper protective equipment.
- Emergency procedures: Not applicable
- If required, notify relevant authorities according to all applicable regulations.

#### **6.1.2. For emergency responders**

- Must work against the wind, let the upwind people to evacuate.
- Do not touch spilled material. Stop leak if you can do it without risk.
- Handling the damaged containers or spilled material after wearing protective equipment.
- Do not direct water at spill or source of leak.
- Avoid skin contact and inhalation.

### **6.2. Environmental precautions**

- Prevent runoff and contact with waterways, drains or sewers.
- If large amounts have been spilled, inform the relevant authorities.
- Avoid dispersal of spilt material and runoff and contact with waterways, drains and sewers. If large spills, advise emergency services.

### 6.3. Methods and material for containment and cleaning up

#### 6.3.1. For containment

- Don't use a brush or compressed air for cleaning surfaces or clothing.
- Clean up all spills immediately.
- Clear area of personnel and move up wind.

#### 6.3.2. For cleaning up

- Large spill : Stay upwind and keep out of low areas. Dike for later disposal.
- Notification to central government, local government. When emissions at least of the standard amount
- Dispose of waste in accordance with local regulation.
- Appropriate container for disposal of spilled material collected.
- Small leak: sand or other non-combustible material, please let use absorption.
- Wipe off the solvent.
- Dike for later disposal.

#### 6.3.3. Other information

- Slippery when spilt.

### 6.4. Reference to other sections

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protection equipment.
- See Section 13 for information on disposal.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

- Avoid direct physical contact.
- Since emptied containers retain product residue(vapor, liquid, solid) follow all MSDS and label warnings even after container is emptied.
- Comply with all applicable laws and regulations for handling
- Dealing only with a well-ventilated place.
- Do not inhale the steam prolonged or repeated.

### 7.2. Conditions for safe storage, including any incompatibilities

- Save applicable laws and regulations.
- Do not apply any physical shock to container.
- Avoid direct sunlight.
- Keep in the original container.
- Please pay attention to incompatibilities materials and conditions to avoid.

### 7.3. Specific end use(s)

- See Section 1 for information on 1.2 Relevant identified uses.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### 8.1.1. Occupational exposure limits

##### European Union (EU) Commission Directive 2006/15/EC (IOELVs)

- Not available

##### European Union (EU) Commission Directive 2006/15/EC (IOELVs) - Skin

- Not available

#### 8.1.2. Recommended Monitoring Procedures

- Personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.

#### 8.1.3. DNEL/PNEC - Values

- Not available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

- A system of local and/or general exhaust is recommended to keep employee exposures above the Exposure Limits. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. The use of local exhaust ventilation is recommended to control emissions near the source.

### 8.2.2. Individual protection measures, such as personal protective equipment

#### Hand protection

- Wear appropriate glove.

#### Eye protection

- Wear primary eye protection such as splash resistant safety goggles with a secondary protection face shield.
- Provide an emergency eye wash station and quick drench shower in the immediate work area.

#### Respiratory Protection

- Under conditions of frequent use or heavy exposure, Respiratory protection may be needed.
- Respiratory protection is ranked in order from minimum to maximum.
- Consider warning properties before use.
- Any chemical cartridge respirator with organic vapor cartridge(s).
- Any chemical cartridge respirator with a full facepiece and organic vapor cartridge(s).
- Any air-purifying respirator with a full facepiece and an organic vapor canister.
- For Unknown Concentration or Immediately Dangerous to Life or Health : Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply. Any self-contained breathing apparatus with a full facepiece.

#### Skin protection

- Wear appropriate clothing.

#### Others

- It is necessary to wear protective clothes and other protection equipment. Cover your face, head and neck.
- Prior to removing protective garments the employee should undergo decontamination and be required to shower upon removal of the garments and hood.
- Emergency deluge showers and eyewash fountains, supplied with potable water, should be located near, within sight of, and on the same level with locations where direct exposure is likely.

#### Thermal hazards

- Not available

### 8.2.3 Environmental exposure controls

- Do not let product enter drains. For ecological information refer to section 12.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

	Appearance	Odor
Wash Buffer	Colorless, Liquid	Odorless
TMB Chromogen	Colorless or light blue, Liquid	Odorless
Stop Solution	Colorless, Liquid	Odorless
Sample Diluent	Red, Liquid	Odorless
Antigen Diluent Buffer	Colorless, Liquid	Odorless
Dengue 1-4 Antigen	Blue green, Liquid	Odorless
Dengue IgM Capture MAb Tracer HRP	Yellow, Liquid	Odorless
Dengue IgM Capture Control	Colorless or faint yellow, Liquid	Odorless

### 9.2. Other information

- Not available

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

- Not available

### 10.2. Chemical Stability and Reactivity

- This material is stable under recommended storage and handling conditions.

**10.3. Possibility of hazardous reactions**

- Hazardous Polymerization will not occur.

**10.4. Conditions to avoid**

- Avoid contact with incompatible materials and condition.
- Avoid : Accumulation of electrostatic charges, Heating, Flames and hot surfaces

**10.5. Incompatible materials**

- Not available

**10.6. Hazardous decomposition products**

- May emit flammable vapour if involved in fire.

**SECTION 11: TOXICOLOGICAL INFORMATION****11.1. Acute toxicity****- Oral**

- [Water] : LD<sub>50</sub> = 90000 mg/kg Rat
- [Gentamycin sulfate] : LD<sub>50</sub> > 5000 mg/kg Rat
- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] : LD<sub>50</sub> = 50 ~ 300 mg/L
- [Sodium azide] : LD<sub>50</sub> = 5 ~ 50 mg/L

**- Dermal**

- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] : LD<sub>50</sub> = 200 ~ 1000 mg/L

**- Inhalation**

- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] : LC<sub>50</sub> = 2 ~ 10 mg/L

**11.2. Skin corrosion/irritation**

- Causes skin irritation

**11.3. Eye corrosion/irritation**

- Causes serious eye irritation

**11.4. Respiratory sensitization**

- Not available

**11.5. Skin sensitization**

- May cause an allergic skin reaction

**11.6. Mutagenicity**

- Not available

**11.7. Carcinogenicity****- IARC**

- Not available

**- OSHA**

- Not available

**- ACGIH**

- [Sodium azide] : A4

**- NTP**

- Not available

**- EU CLP**

- Not available

**11.8. Reproductive toxicity**

- Not available

**11.9. Specific target organ toxicity(single exposure):**

- Not available

**11.10. Specific target organ toxicity(repeated exposure):**

- Not available

**11.11. Aspiration hazard**

- Not available

**SECTION 12: ECOLOGICAL INFORMATION****12.1. Toxicity****12.1.1. Fish**

- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] :  $LC_{50}(96hr) \leq 1$  (mg/L)
- [Sodium azide] :  $LC_{50}(96hr) \leq 1$  (mg/L)

**12.1.2. Invertebrate**

- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] :  $EC_{50}(48hr) \leq 1$  (mg/L)
- [Sodium azide] :  $EC_{50}(48hr) \leq 1$  (mg/L)

**12.1.3. Algae**

- [reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1)] :  $ErC_{50}(72 \text{ or } 96hr) \leq 1$  (mg/L)
- [Sodium azide] :  $ErC_{50}(72 \text{ or } 96hr) \leq 1$  (mg/L)

**12.2. Persistence and degradability****12.2.1. Persistence**

- [Water] :  $\log Kow = -1.38$

**12.2.2. Degradability**

- Not available

**12.3. Bioaccumulative potential****12.3.1. Bioaccumulation**

- Not available

**12.3.2. Biodegradability**

- Not available

**12.4. Mobility in soil**

- Not available

**12.5. Results of PBT and vPvB assessment**

- Not available

**12.6. Other adverse effects**

- Not available

**SECTION 13: DISPOSAL CONSIDERATIONS****13.1. Waste treatment methods**

- Since more than two kinds of designaed waste is mixed, it is difficult to treat seperatly, then can be reduction or stabilization by incineration or similar process.
- If water separation is possible, pre-process with Water separation process.
- Dispose by incineration.
- The user of this product must disposal by oneself or entrust to waste disposer or person who other's waste recycle and dispose, person who establish and operate waste disposal facilities.
- Dispose of waste in accordance with all applicable laws and regulations.

**SECTION 14: TRANSPORT INFORMATION****14.1. UN No.****14.1.1. UN No. (ADR/RID/ADN)**

- Not available

**14.1.2. UN No. (IMDG)**

- Not available

**14.1.3. UN No. (ICAO)**

- Not available

**14.2. UN proper shipping name**

- Not available

**14.3. Transport hazard class(es)****14.3.1. ADR/RID/ADN Class**

- Not available

**14.3.2. ADR/RID/ADN Class**

- Not available

**14.3.3. ADR Label No.**

- Not available

**14.3.4. IMDG Class**

- Not available

**14.3.5. ICAO Class/Division**

- Not available

**14.3.6. Transport Labels**

- Not available

**14.4. Packing group****14.4.1. ADR/RID/ADN Packing group**

- Not available

**14.4.2. IMDG Packing group**

- Not available

**14.4.3. ICAO Packing group**

- Not available

**14.5. Environmental hazards**

- Not applicable

**14.6. Special precautions for user**

- Local transport follows in accordance with Dangerous goods Safety Management Law.
- Package and transport follow in accordance with Department of Transportation (DOT) and other regulatory agency requirements.
- EmS FIRE SCHEDULE : Not available
- EmS SPILLAGE SCHEDULE : Not available

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

- Not available

**SECTION 15: REGULATORY INFORMATION****15.1. Safety, health and environmental regulation / legislation specific for the substance or mixture****15.1.1. Europe regulatory****REACH Restricted substance under REACH**

- Not applicable

**REACH Substances subject to authorization under REACH**

- Not applicable

**REACH SVHC**

- Not applicable



**Europe PBT**

- Not applicable

**European Union (EU) Transport of Dangerous Goods by Road - Dangerous Goods List**

- Not applicable

**EU classification[Regulation (EC) No 1272/2008 Annex VI Table 3.1]**

- Applicable (reaction mass of: 5-chloro-2- methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3- one (3:1))

**Germ cell mutagenicity(Mutagen)**

- Not applicable

**Reproductive toxicity(Reproductive)**

- Not applicable

**15.2. Chemical Safety Assessment**

- Not conducted

**SECTION 16: OTHER INFORMATION****16.1. Indication of changes**

- The Safety Data Sheet has been reviewed and the data therein were revised and laid out according the requirements of the Commission Regulation (EU) No. 453/2010

**16.2. Abbreviations and acronyms**

- 1272/2008 CLP : Classification, Labelling and Packaging regulation.
- REACH : Registration, Evaluation and authorisation of chemical substances.
- DNEL : Derive no effects level
- PNEC : Predicted no effect concentration

**16.3. Key literature references and sources for data**

- This Safety Data Sheet was compiled with data and information from the following sources: RTECS, ECOSAR, HSDB, SIDS SIAP, ChemWATCH, CESAR, Chemical DB

**16.4. Relevant H and P statements**

- See Section 2.1 for information on Classification of the mixture.

**16.5. Training advice**

- Not applicable

**16.6. Further information**

- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.
- This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only.
- It should not therefore be construed as guaranteeing any specific property of the product.