



## Material Safety Data Sheet

# Dengue NS1 Antigen

ELISA

IDENTIFICATION OF THE PREPARATION AND COMPANY NAME.

Product Name: Dengue NS1 Antigen ELISA  
Catalog No: 8404-25  
Synonyms: N/A  
Product Description: Diagnostic Kit for Dengue Infection

Intended Use: Laboratory Use      Kit Storage:  2-8°

### SECTION 1. HAZARD IDENTIFICATION

· **Classification of the substance or mixture:**

The product does not need classification according to OSHA HazCom Standard 29 CFR paragraph (d) of §1910.1200(g) and GHS Rev 03.

· **Label elements:**

- **GHS label elements:** Non-Regulated Material
- **Hazard pictograms:** Non-Regulated Material
- **Signal word:** Non-Regulated Material
- **Hazard statements:** Non-Regulated Material

· **Unknown acute toxicity:**

0 % of the mixture consists of component(s) of unknown toxicity.

· **Classification system:**

**NFPA ratings (scale 0-4)**

HMIS HEALTH	0
HMIS FIRE	0
HMIS REACTIVITY	0

**HIMIS-ratings: (scale 0-4)**

HMIS HEALTH	0
HMIS FIRE	0
HMIS REACTIVITY	0

Hazard(s) not otherwise classified (HNOC): None known

### SECTION 2. Composition/Information on Ingredients

**Coated Microtiter Strips:**

- **Description:** Mixture: consisting of non-regulated material.
- **Dangerous Components:** Non-Regulated Material

**Liquid TMB Substrate:**

- **Description:** Mixture: consisting of non-regulated material.
- **Dangerous Components:** Non-Regulated Material

**Cut-Off Control:**

- **Description:** Mixture: consisting of non-regulated material.
- **Dangerous Components:** Non-Regulated Material

**Positive Control:**

- **Description:** Mixture: consisting of non-regulated material.
- **Dangerous Components:** Non-Regulated Material

**Sample Dilution Buffer:**

- **Description:** Mixture: consisting of non-regulated material.

· **Dangerous Components:** Non-Regulated Material




**Negative Control:**

· **Chemical characterization: Substance**

· **CAS No. Description**

Human Serum (normal)



**Conjugate Diluent:**

· <b>Dangerous Components:</b>		
9002-93-1	Triton X-100	≤2.5%
	 Acute Tox. 3, H331;  Aquatic Acute 1, H400; Aquatic Chronic 1, H410;  Acute Tox. 4, H302 Eye Irrit. 2A, H319	

**100X Conjugate:**


· <b>Dangerous Components:</b>		
CAS: 56-81-5 RTECS: MA 8050000	Glycerol	≤2.5%

**10x Wash Buffer:**

· <b>Dangerous Components:</b>		
CAS: 7647-14-5 RTECS: VZ4725000	Sodium Chloride  STOT SE 3, H335	5-10%
CAS: 7558-79-4 RTECS: WC 4500000	Sodium Phosphate  Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335-H336	≤2.5%

**Stop Solution:**

· **Description:** Mixture of substances listed below with non-hazardous additions.

· <b>Dangerous Components:</b>			
7664-93-9	Sulfuric Acid	 Skin Corr. 1A, H314	2-12%

**SECTION 3. FIRST AID MEASURES**

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**  
Generally the product does not irritate the skin. If skin irritation occurs, consult a doctor.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. If eye irritation occurs, consult a doctor.
- **After swallowing:** If swallowed and symptoms occur, consult a doctor.
- **Information for doctor:** N/A
- **Most important symptoms and effects, both acute and delayed:** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed:**  
No further relevant information available.

**SECTION 4. FIRE-FIGHTING MEASURES**

- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters:**
  - **Protective equipment:**  
As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent) and full protective gear to prevent contact with skin and eyes.

**SECTION 5. ACCIDENTAL RELEASE MEASURES**

- **Personal precautions, protective equipment and emergency procedures:** Not required.
- **Environmental precautions:** Dilute with plenty of water. Do not allow to enter sewers/surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dispose of the collected material according to regulations.  
Absorb with liquid-binding material (i.e sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections:**  
See Section 6 for information on safe handling.  
See Section 7 for information on personal protection equipment.  
See Section 12 for disposal information.

**SECTION 6. HANDLING AND STORAGE**

- **Precautions for safe handling:** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s):** No further relevant information available.

**SECTION 7. EXPOSURE CONTROL / PERSONAL PROTECTION**

- **Additional information about design of technical systems:** No further data; see section 6.
- **Control parameters:**

**100X Conjugate**

· <b>Components with occupational exposure limits:</b>	
<b>56-81-5 Glycerol</b>	
PEL	Long-term value: 15* 5** mg/m <sup>3</sup> mist; *total dust **respirable fraction
TLV	TLV withdrawn-sufficient data human occup. exp.

**Stop Solution:**

· <b>Components with occupational exposure limits:</b>	
<b>7664-93-9 Sulfuric Acid</b>	
PEL	Long-term value: 1mg/m <sup>3</sup>
REL	Long-term value: 1mg/m <sup>3</sup>
TLV	Long-term value: 0.2* mg/m <sup>3</sup> *as thoracic fraction

**Other Components:**

- **Components with occupational exposure limits:** The rest of the product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
- **Exposure controls:**
  - **General protective and hygienic measures:**  
The usual precautionary measures for handling chemicals should be followed.
  - **Breathing equipment:** Not required.
  - **Protection of hands:**



Protective gloves.

- **Material of gloves:** Nitrile rubber, NBR.
- **Penetration time of glove material:** The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.
- **Eye protection:**



Goggles recommended during refilling.

**SECTION 8. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

	Coated microtiter strips	Negative - control	Positive + control	Cut-off control	Sample diluent	100X Conjugate	Conjugate diluent	10X Wash buffer	TMB substrate	Stop sol.
Form	Strips	Liquid								
Color	Clear									
Odor	None	Slight	None							
Melting/boiling points	Not determined									
	Coated microtiter strips	Negative - control	Positive + control	Cut-off control	Sample diluent	100X Conjugate	Conjugate diluent	10X Wash buffer	TMB substrate	Stop sol.
Flash point	None									
pH at 20°C	N/A	7-8	7	Not determined						
Vapor pressure at 20°C	N/A	Not determined	23 hPa	23 hPa	Not determined			23 hPa	Not determined	
Density at 20°C	N/A		1.009 g/cm <sup>3</sup>	1 g/cm <sup>3</sup>	Not determined					
Explosion hazard	Products do not present explosion hazards.									
Auto igniting	Products are not self-igniting.									
Solubility/Miscibility in Water	Insoluble	Fully miscible.								
Organic solvents	0%					1%	0%			

**SECTION 9. STABILITY AND REACTIVITY**

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** Strong oxidizing agents.
- **Hazardous decomposition products:** No dangerous decomposition products known.

**SECTION 10. TOXICOLOGICAL INFORMATION**

- **Information on toxicological effects:**
- **Acute toxicity:**

**LD/LC50 values that are relevant for classification:**

<b>9002-93-1 Triton X-100</b>		
Oral	LD50	1800mg/kg (rat)
Dermal	LD50	8000mg/kg (rat)
Inhalative	LC50/4 hours	8.9 mg/l (Pimephales)
<b>7647-14-5 Sodium Chloride</b>		
Oral	LD50	4000 mg/kg (mouse) 3000 mg/kg (rat)
Dermal	LD50	>10000 mg/kg (rabbit)
<b>7558-79-4 Sodium Phosphate</b>		
Oral	LD50	17000 mg/kg (rat)
<b>7664-93-9 Sulfuric Acid</b>		
Oral	LD50 Oral	2140 ml/kg (rat)
Inhalative	LC50/96 hours	375 mg/l (rat)
Sulfuric acid is harmful by all routes of entry		

· **Primary irritant effect:**

- **On the skin:** May be irritating.
- **On the eye:** May be irritating.

· **Additional toxicological information:**

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories:**

· **IARC (International Agency for Research on Cancer):**

- Group 1 – Carcinogenic to humans
- Group 2A – Probably carcinogenic to humans
- Group 2B – Possibly carcinogenic to humans
- Group 3 – Not classifiable as to its carcinogenicity to humans
- Group 4 – Probably not carcinogenic to humans

7647-01-0	Hydrochloric acid	3
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· **NTP (National Toxicology Program):**

None of the ingredients are listed.

· **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

**SECTION 11. ECOLOGICAL INFORMATION**

· **Aquatic toxicity:**

**9002-93-1 Triton X-100**

EC50 26 mg/l (daphnia)

**7664-93-9 Sulfuric Acid**

EC50 22 mg/l (daphnia)

**7647-14-5 Sodium Chloride**

EC50 340.7-469.2 mg/l (Water flea)

· **Persistence and degradability:** No further relevant information available.

· **Behavior in environmental systems:**

- **Bioaccumulative potential:** No further relevant information available.
- **Mobility in soil:** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.

- **Results of PBT and vPvB assessment:**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

**SECTION 12. DISPOSAL CONSIDERATIONS**

- **Waste treatment methods:**
- **Recommendation:**
  - Smaller quantities can be disposed of with household waste.
  - Observe all federal, state and local environmental regulations when disposing of this material.
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

**SECTION 13. TRANSPORT INFORMATION**

· <b>UN-Number:</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	Non-Regulated Material
· <b>UN proper shipping name:</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	Non-Regulated Material
· <b>Transport hazard class(es):</b>	
· <b>DOT, ADR, ADN, IMDG, IATA</b>	
· <b>Class:</b>	Non-Regulated Material
· <b>Packing group:</b>	
· <b>DOT, ADR, IMDG, IATA</b>	Non-Regulated Material
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user:</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:</b>	Not applicable.
· <b>UN "Model Regulation":</b>	Non-Regulated Material

**SECTION 14. REGULATORY INFORMATION**

- **SARA (Superfund Amendments and Reauthorization):**

· **Section 355 (extremely hazardous substances):**

7647-01-0	Hydrochloric acid
7664-93-9	Sulfuric Acid

- **Section 313 (Specific toxic chemical listings):**

7647-01-0	Hydrochloric acid
7664-93-9	Sulfuric Acid

- **TSCA (Toxic Substances Control Act):**

7732-18-5	Highly Purified Water
7647-14-5	Sodium Chloride
1185-53-1	Tris-HCl
7558-79-4	Sodium Phosphate
9002-93-1	Triton X-100

- **California Proposition 65:**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.



· <b>Chemicals known to cause reproductive toxicity for males:</b>
None of the ingredients are listed.
· <b>Chemicals known to cause developmental toxicity:</b>
None of the ingredients are listed.

· <b>Carcinogenic categories:</b>
· <b>EPA (Environmental Protection Agency):</b>
None of the ingredients are listed.
· <b>TLV (Threshold Limit Value established by ACGIH):</b>
7647-01-0   Hydrochloric acid   A4
7664-93-9   Sulfuric acid   A2
· <b>NIOSH-Ca (National Institute for Occupational Safety and Health):</b>
None of the ingredients are listed.

- **GHS label elements** Non-Regulated Material
- **Hazard pictograms:** Non-Regulated Material
- **Signal word:** Non-Regulated Material
- **Hazard statements:** Non-Regulated Material

· <b>National regulations:</b>
The product is subject to be classified according with the latest version of the regulations on hazardous substances.

· **State Right to Know:**

**Coated Microtiter Strips**

CAS: 7732-18-5	Highly purified water	60%-90%
	Dengue IgG Positive Serum	15%-35%
	Goat Serum	2-12%
CAS: 7647-14-5 RTECS: VZ4725000	Sodium Chloride ⚠ STOT SE 3, H335	≤ 2.5%
CAS: 1185-53-1	Tris-HCl ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	≤ 2.5%

**Negative control:**

None of the ingredients are listed
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**Positive control:**

CAS: 7732-18-5	Highly Purified Water	90-99%
CAS: 9048-46-8	Bovine Serum Albumin	≤ 2.5%
CAS: 7647-14-5	Sodium chloride	≤ 2.5%
CAS: 7558-79-4 RTECS: WC 4500000	Sodium phosphate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335-H336	≤ 2.5%

**Cut-Off control:**

CAS: 7732-18-5	Highly Purified Water Dengue Positive Serum Bovine Serum Albumin	90-99% 2-12% ≤ 2.5%
CAS: 7647-14-5 RTECS: VZ4725000	Sodium chloride ⚠ STOT SE 3, H335	≤ 2.5%
CAS: 7558-79-4 RTECS: WC 4500000	Sodium phosphate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335-H336	≤ 2.5%

**Sample diluent:**

CAS: 7732-18-5	Highly Purified Water	90-99%
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	Goat Serum	2-12%
CAS: 7647-14-5	Sodium chloride	≤ 2.5%
CAS: 1185-53-1	Tris-HCl ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	≤ 2.5%

**100X Conjugate:**

CAS: 7732-18-5	Highly Purified Water	90-99%
CAS: 56-81-5 RTECS: MA 8050000	Glycerol	≤ 2.5%
CAS: 9048-46-8	Bovine Serum Albumin	≤ 2.5%
CAS: 77647-01-0 RTECS: MW 9620000	Hydrochloric acid ⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H332; STOT SE 3, H335	≤ 2.5%
CAS: 77-86-1 RTECS: TY 2900000	Tris base ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	≤ 2.5%

**Conjugate diluent:**

CAS: 7732-18-5	Highly Purified Water Goat Serum	60-90% 5-10%
CAS: 1185-53-1	Tris-HCl ⚠ Skin Irrit. 2, H315; STOT SE 3, H335; Eye Irrit. 2B, H320	≤ 2.5%
CAS: 77-86-1 RTECS: TY 2900000	Triton X-100 ⚠ Acute Tox. 3, H331; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Acute Tox. 4, H302; Eye Irrit. 2A, H319	≤ 2.5%

**10X Wash buffer:**

CAS: 7732-18-5	Highly Purified Water	60-90%
CAS: 7647-14-5 RTECS: VZ4725000	Sodium chloride ⚠ STOT SE 3, H335	5-10%
CAS: 7558-79-4 RTECS: WC 4500000	Sodium phosphate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2A, H319; STOT SE 3, H335-H336	≤ 2.5%
CAS: 9005-64-5 RTECS: TR7400000	Tween 20	≤ 2.5%

**TMB Substrate:**

CAS: 7732-18-5	Highly Purified Water	90-99%
CAS: 7664-93-9	Sulfuric Acid ⚠ Skin Corr. 1A, H314	2-12%

**Stop Solution:**

CAS: 7732-18-5	Highly Purified Water	90-99%
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· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 15. OTHERS**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Last revision:** 4

· **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road  
 ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways  
 IMDG: International Maritime Code for Dangerous Goods



DOT: US Department of Transportation  
 IATA: International Air Transport Association  
 ACGIH: American Conference of Governmental Industrial Hygienists  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent



EINECS: European Inventory of Existing Commercial Chemical Substances  
 ELINCS: European List of Notified Chemical Substances  
 CAS: Chemical Abstracts Service (division of the American Chemical Society)  
 NFPA: National Fire Protection Association (USA)  
 HMIS: Hazardous Materials Identification System (USA)  
 PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative  
 NIOSH: National Institute for Occupational Safety  
 OSHA: Occupational Safety & Health  
 TLV: Threshold Limit Value  
 PEL: Permissible Exposure Limit  
 REL: Recommended Exposure Limit  
 STOT SE: Specific target organ toxicity – Single exposure

***\*Data compared to the previous version altered.***

<p><b>ISO 13485</b> <b>ISO 9001</b></p> 	
 <p><b>Diagnostic Automation/Cortez Diagnostics,          Inc.</b>  <b>21250 Califa Street, Suite 102 and 116,          Woodland Hills, California 91367 USA</b></p>	
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Revision #:4: 2016-02-03	