

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY**1.1 Product identifier**Product Name: DIASpot Neptune ENA⁶ IgG

Catalog #: KAPDTENAN

Kit Components: Diluent Buffer
Wash Buffer
Conjugate
Substrate
Dot Strips
Cartridge**1.2 Intended Use**

Immunodot kit (professional IVD use only, automated on the Neptune Instrument) for the detection of IgG antibodies to Sm, Sm/RNP, SSA/Ro60kD, SSB, Jo-1 and Scl-70 antigens in human serum.

1.3 CompanyDIAsource ImmunoAssays S.A.
Rue du Bosquet, 2
B-1348 Louvain-la-Neuve
Belgium
Tel. Nr. +32 (0)10/84.99.11
E-mail: products.support@diasource.be**1.4 Emergency telephone**DIAsource (only office hours): +32 (0)10/84.99.11
Centre Anti-Poisons (BE) 070 245 245
Please refer to your local Anti-Poison Center!**2 HAZARDS IDENTIFICATION****2.1 Classification of the substance or mixture**According to *Regulation (EC) N° 1272/2008* the preparation is not classified as dangerous.**2.2 Label elements**According to *Regulation (EC) N° 1272/2008*: none**2.3 Other hazards**

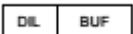
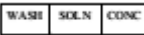
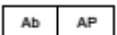


The products / product components contain preservatives which may possess in their given concentration, skin-sensitizing and slightly polluting properties. As any chemicals contain specific hazards, the products / product components should only be handled by appropriately trained personnel and with the necessary precautions for chemicals.

3 COMPOSITION/INFORMATION ON INGREDIENTS
3.1 Substances

N/A (see hereunder: mixture)

3.2 Mixtures

Abbreviation	Substance	Abbreviation	Substance
AP	Alkaline Phosphatase	NBT	NitroBlueTetrazolium
BCIP	Bromo-Chloro-Indolyl-Phosphate	TBS	Tris Buffer Saline
MIT	MethylIsoThiazolone (preservative)		

Contents	Quantity	Ingredients
1. Cartridge	24 units having each 7 compartments (Position I to VII); sealed, containing:	
Sample Buffer 	Position I, 1 x 1,4 mL (yellow)	TBS, Sodium Chloride, Tween 20, Dye, MIT, antifoam emulsion
Wash Buffer 	Position II, III, IV, VI, 1 x 1,4 mL (colourless)	TBS, Sodium Chloride, Tween 20, MIT, antifoam emulsion
Conjugate 	Position V, 1 x 1,4 mL (red)	TBS, Sodium Chloride, Potassium Chloride, Magnesium Chloride, Goat anti-human IgG/AP, Dye, MIT, antifoam emulsion
Substrate 	Position VII, 1 x 1,4 mL (pale yellow)	TBS, Magnesium Chloride, BCIP, NBT, NBT Stabilizer, Sodium Azide, antifoam emulsion
2. Strips	3 x 8 units on plastic supports, breakable individually; sealed	
Membrane Strip 	8 dots on each: 1 positive control (C+) 6 antigens 1 negative control (C-)	Membrane-coated with purified antigens: Sm (purified from bovine thymus), Sm/RNP (purified from bovine thymus), SSA/Ro60kD (60kD, human recombinant), SSB (recombinant, human), Jo-1 (recombinant, human) and Scl-70 (recombinant, human)

Hazardous Substances and their concentrations

The Hazard Classification listed in this section refers to the chemical at *a pure concentration*. It has been determined that the remaining ingredient(s) of these components are not classified as hazardous chemicals due to their physical and/or chemical nature and/or concentration in solution (see concentration here in the table).

Name	CAS	EINECS	Concentration in mixture	Classification (in concentrated form) according to Regulation	
				1999-45/EC Significance R Phrases	EC 1272/2008 Significance H Phrases
MIT	55965-84-9	-	< 0,0015 %	T R23/24/25; R34; R43	Acute tox. 3 H331, H311, H301 Skin Corr. 1B. H314 Skin Sens. 1 H317
				N R50/53	Aquatic acute 1 ; Aquatic chronic 1 H410

Annex VI to Regulation (EC) No 1272/2008: Index N°: 613-167-00-5

Name	CAS	EINECS	Concentration in mixture	Classification (in concentrated form) according to Regulation	
				1999-45/EC Significance R Phrases	EC 1272/2008 Significance H Phrases
NBT	298-83-9	206-067-4	< 0,01%	Xn (Nocif) R20/R22	Acute tox. 4 H302

Name	CAS	EINECS	Concentration in mixture	Classification (in concentrated form) according to Regulation	
				1999-45/EC Significance R Phrases	EC 1272/2008 Significance H Phrases
Sodium Azide	26628-22-8	247-852-1	< 0.1 %	T+ R28; R32	Acute tox. 2 H300
				N R50/53	Aquatic acute 1 H400

Annex VI to Regulation (EC) No 1272/2008: Index Number: 011-004-00-7

Abbreviations and significances:

CAS: Chemical Abstract Service (division of the American Chemical Society)

EINECS: European Inventory of Existing Commercial Chemical Substances

C: **N:**dangerous for the **T:**toxic **T+:**very **Xn:**harmful

Information on significance of R and H Phrases: see Section 16

4 FIRST AID MEASURES

	SYMPTOMS	FIRST AID
Contact with eyes:	Irritation. Tears	Immediately flush eyes large volume of water.
Contact with skin:	Irritation	Immediately wash skin with soap and thoroughly with water.
Ingestion:	It is recommended to avoid ingestion and contact with food	If swallowed, wash out mouth with water provided the person is conscious; seek medical advice (showing this document when possible). Never give anything by mouth to an unconscious person; never try to make an unconscious person vomit.

5 FIRE FIGHTING MEASURES

Flammability:	Liquid reagents contained in the kit are not flammable. Combustion of cardboard inserts inside the kit and the outer cardboard box of the kit may produce intense heat.
Extinguishing Media:	Water, carbon dioxide, dry chemical powder or polymer foam. Use extinguishing media appropriate to surrounding fire conditions.
Special Fire Fighting Procedures:	For fires involving this material, do not enter any enclosed or confined fire space without proper protective equipment. This may include self-contained breathing apparatus to protect against the hazardous effects of the normal products of combustion or oxygen deficiency.

6 ACCIDENTAL RELEASE MEASURES
6.1 Personal Precautions

Always observe GLP (Good Laboratory Practice) safety lines. To avoid contact with skin and eyes wear appropriate protective clothing. Do not swallow, do not pipette by mouth.

6.2 Environmental Precautions

Avoid flushing away in drains; keep away from surface- and ground-water; keep away from soil.

6.3 Methods and material for containment and cleaning up

Sweep up and collect in appropriate containers for waste disposal; clean the floor and all other contaminated objects with water.

6.4 Reference to other sections

N/A

7 HANDLING AND STORAGE
7.1 Precautions for safe handling

Always observe GLP (Good Laboratory Practice) safety lines. Wear appropriate protective clothing (refer to point 8.2). Wash hands and any other exposed zones with water and mild soap before eating, drinking, smoking and leaving workplace. Check the local and general ventilation of the workplace. Take any measures to prevent aerosol and dust generation and fire. Dispose of the waste according to safety measures of GLP.

7.2 Conditions for safe storage, including any incompatibilities

Always store the product according to instructions given on the label.

Always observe given temperature and humidity limit/range.

7.3 Specific end use(s)

N/A

8 EXPOSURE CONTROLS/PERSONAL PROTECTION
8.1 Control parameters

Name	Comment
MIT	Contains no substances with occupational exposure limit values
NBT	Contains no substances with occupational exposure limit values
Sodium Azide	TWA value 0,1 mg/m ³ (in EU)

TWA: Time Weighted Average, i.e. the average exposure to a contaminant to which workers may be exposed without adverse effect over a period such as in an 8-hour day or 40-hour week (an average work shift). They are usually expressed in units of ppm (volume/volume) or mg/m³.

8.2 Exposure controls

Respiratory protection:	None
Gloves:	Laboratory nitrile or latex gloves
Eye protection:	Goggles
Skin protection	Laboratory coat

9 PHYSICAL AND CHEMICAL PROPERTIES
9.1 Information on basic physical and chemical properties

	Kit Reagent				
	DIL	BUF	WASH SOLN CONC	Ab AP	SUB
Appearance:	Liquid reagent Colour: yellow	Liquid reagent Colour: colourless	Liquid reagent Colour: red	Liquid reagent Colour: pale yellow	Liquid reagent Colour: pale yellow
Odour:	Negligible	Negligible	Negligible	Negligible	Negligible
Odour threshold:	Not given	Not given	Not given	Not given	Not given
pH value:	Not given	Not given	Not given	Not given	Not given
Melting point/freezing point:	Not given	Not given	Not given	Not given	Not given
Initial boiling point and boiling range:	Not given	Not given	Not given	Not given	Not given
Flash point:	N/A	N/A	N/A	N/A	N/A
Evaporation rate:	N/A	N/A	N/A	N/A	N/A
Flammability :	N/A	N/A	N/A	N/A	N/A
Upper/lower flammability or explosive limits:	Not explosive	Not explosive	Not explosive	Not explosive	Not explosive
Vapour pressure:	Not given	Not given	Not given	Not given	Not given
Vapour density:	Not given	Not given	Not given	Not given	Not given
Relative density:	Not given	Not given	Not given	Not given	Not given
Solubility:	Completely soluble	Completely soluble	Completely soluble	Completely soluble	Completely soluble
Partition coefficient n-octanol/water :	Not given	Not given	Not given	Not given	Not given
Auto-ignition temperature :	Not given	Not given	Not given	Not given	Not given
Decomposition temperature :	Not given	Not given	Not given	Not given	Not given
Viscosity :	Not given	Not given	Not given	Not given	Not given
Explosive properties :	Not explosive	Not explosive	Not explosive	Not explosive	Not explosive

	Kit Reagent							
	DIL	BUF	WASH	SOLN	CONC	Ab	AP	SUB
Oxidizing properties :	Not given		Not given		Not given		Not given	

9.2 Other information

N/A

10 STABILITY AND REACTIVITY

10.1 Reactivity

Particular dangerous reactions not known

10.2 Chemical stability

Materials to avoid: None.

Chemical stability: If storage conditions and expiry date are correctly observed, the mixture / product components are chemically stable.

10.3 Possibility of hazardous reactions

Sodium Azide (in high concentrations) reacts with heavy metals such as copper or lead and forms explosive compounds.

10.4 Conditions to avoid

Avoid inappropriate storage (temperature, humidity, light, etc).

Avoid inappropriate use.

10.5 Incompatible materials

Acids, alkalis and solvents may adversely affect the functionality of the mixtures / product components.

10.6 Hazardous decomposition products

Under appropriate storage conditions and correct handling of the mixtures / product components, hazardous decomposition products are not known.

Combustion of cardboard inserts inside the kit and of the outer cardboard box of the kit does not liberate toxic gas (only carbon dioxide and water vapour).

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Ingredient	Measured quantity	Value	Species
MIT	LD ₅₀ (oral)	-	-
NBT	LD ₅₀ (oral)	2000 mg/kg	Mouse
Sodium Azide	LD ₅₀ (oral)	27 mg/kg	Rat

LD₅₀ test: Lethal dose for 50% of the population of test animals

Other health effects

Ingredient	Irritation and corrosivity	Sensitization	CMR
MIT	No data available	No data available	No data available
NBT	No data available	No data available	No data available
Sodium Azide	No data available	No data available	No data available

CMR: carcinogenic, mutagenic or toxic for reproduction

12 ECOLOGICAL INFORMATION
12.1 Toxicity

Ingredient	Toxicity for algae	Toxicity for daphnia	Toxicity for fish	Toxicity for microorganisms
MIT	-	-	-	-
NBT	-	-	-	-
Sodium Azide	-	-	LC50= 0.8 mg/L <i>Oncorhynchus mykiss</i> 96 h LC50= 0.7 mg/L <i>Lepomis macrochirus</i> 96 h LC50=5.46 mg/L <i>Pimephalespromelas</i> 96 h	-

LC50 test: (Lethal Concentration 50) Standard measure of the toxicity of the surrounding medium that will kill 50 % of the sample population in a specified period through exposure via inhalation (respiration). LC50 is measured in micrograms (or milligrams) of the material per liter, or parts per million (ppm), of air or water.

12.2 Persistence and degradability

Ingredient	Measured quantity	Value	Comment
MIT	No data available	-	-
NBT	No data available	-	-
Sodium Azide	No data available	-	-

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPVB assessment

N/A

12.6 Other adverse effects

Ingredient	Effect
MIT	Very toxic to aquatic organisms, may cause long-term adverse effects
NBT	No data available
Sodium Azide	Very toxic to aquatic organisms

Due to the very low concentration of the toxic substance in the mixture / product ingredients, the handling and use of it do not lead to ecological problems.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Emptied cartridges and used strips may retain product residues: always handle as if they were full. Chemical waste cannot be disposed of with household garbage: please contact a licensed professional waste disposal service to dispose of this material.

The waste generated by chemical preparations has generally to be regarded as special waste material, and is in most countries regulated by federal or state government laws and ordinances. Please contact the authority in the matter.

13.2 Disposal of the packaging

Used cartridges must be treated as chemical waste (see above). Disposal always according to official regulations: please contact the authority in the matter.

14 TRANSPORT INFORMATION

N/A: The products are not subject to transport regulations.

15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The user has to observe the applicable regulations.

Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

Regulation (EC) N° 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC (classification, packaging and labelling of dangerous preparations) and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Commission Regulation (EU) N° 453/2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Regulation (EC) N° 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 OTHER INFORMATION**Hazard phrases**

Code	Phrase
H300	Fatal if swallowed
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H331	Toxic if inhaled
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

Full text of hazard and risk phrases mentioned in this document:

Risk phrases

Code	Phrase
R20/22	Harmful by inhalation and if swallowed
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R28	Very toxic if swallowed
R32	Contact with acids liberates very toxic gas
R34	Causes burns
R43	May cause sensitisation by skin contact
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic

MSDS established : 2023-04-13

Revision number : 2