1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name:	DIASpot Neptune Celiac IgG
Catalog #:	KAPDTENDGN
Kit Components:	Dot strips Cartridge Diluent buffer Wash buffer Conjugate Substrate Absorbent Paper

1.2 Intended Use

Immunodot kit (professional IVD use only, automated on the Neptune Instrument) for the detection of IgG antibodies to the antigens deamidated Gliadin and tissue Transglutaminase (tTG in human serum.

1.3 Company

DIAsource 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; according to concentration and/or conditioning: 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	NaCl	Sodium Chloride
BCIP	Bromo-Chloro-Indolyl-Phosphate	NaN_3	Sodium Azide
BSA	Bovine Serum Albumin	NBT	NitroBlue Tetrazolium
KCl	Potassium Chloride	TBS	Tris Buffer Saline
MgCl2	Magnesium Chloride		
MIT	MethylIsoThiazolone (preservative)		

Contents	Quantity	Ingredients
1. Cartridge	***24 units having each 7 compartments (Position I to VII); sealed, containing:***	
Sample Buffer DIL BUF	Position I, 1 x 1,4 mL (yellow)	H2O, TBS, NaCl, Tween, BSA, MIT, Dye, antifoam emulsion
Wash Buffer WASH SOLN CONC	Position II, III, IV, VI, 1 x 1,4 mL (colourless)	H2O, TBS, NaCl, Tween, MIT, antifoam emulsion
Conjugate Ab AP	Position V, 1 x 1,4 mL (red)	H2O, TBS, NaCl, KCl, MgCL2, AP-conjugated goat anti-human IgG, MIT, Dye, antifoam emulsion
Substrate SUB	Position VII, 1 x 1,4 mL (pale yellow)	H2O, NaN3 (0.05 %), MgCL2, TBS, NBT, BCIP, NBT Stabilizer
2. Strips	***3 x 8 units on plastic supports, breakable individually; sealed***	
Membrane Strip STRIP	4 dots on each: 1 positive control (C+) 2 antigens 1 negative control (C-)	Membrane (cellulose nitrate), coated with purified antigens: **Deamidated gliadin** (purified from wheat gluten) and **tissue Transglutaminase** (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) and/or their conditioning.

Name	CAS	EINECS	Concentration in strip	Classification according to Regulation EC 1272/2008 Significance H Phrases
Cellulose Nitrate	9004-70-0	-	< 5 %	Flam. Sol. 1 H228

Annex VI to Regulation (EC) No 1272/2008: Index N°: 603-037-00-6; Commission Regulation (EU) 2015/830; 3.2.1

Name	CAS	EINECS	Classification

			Concentration in mixture	**(in concentrated form) according to Regulation EC 1272/2008 Significance H Phrases**
MIT:	55965-84-9	-	< 0,0015 %	Acute tox. 3 H331, H311, H301 Skin Corr. 1B. H314 Skin Sens. 1 (C ≥ 0,0015 %) H317 Aquatic acute 1 H400 Aquatic chronic 1 H410

Annex VI to Regulation (EC) No 1272/2008: Index N°: 613-167-00-5; Commission Regulation (EU) 2015/830; 3.2.1

Name	**CAS**	**EINECS**	**Concentration in mixture**	**Classification (in concentrated form) according to Regulation EC 1272/2008 Significance H Phrases**
NaN_3	26628-22-8	247-852-1	< 0.1 %	Acute tox. 2 H300 Acute tox. 1 H310 STOT RE 2 H373 Aquatic acute 1 H400 Aquatic chronic, 1 H410

Annex VI to Regulation (EC) No 1272/2008: Index Number: 011-004-00-7; Commission Regulation (EU) 2015/830; 3.2.1

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

4 FIRST AID MEASURES

	SYMPTOMS	FIRST AID
Contact with eyes:	Irritation. Tears	Immediately flush eyes thoroughly with water.
Contact with skin:	Irritation	Immediately wash skin with soap and large volumes of 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. Cellulose Nitrate in pure form is highly flammable, but due to the small quantity (< 5% of strip) and the conditioning of it not considered as a risk. Combustion of cardboard inserts inside the kit and the outer cardboard box of the kit may produce intense heat.
Extinguishing Media:	Water (for cellulose nitrate strips); water, carbon dioxide, dry chemical powder or polymer foam (for all other ingredients). 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
Cellulose Nitrate	Contains no substances with occupational exposure limit values nor with short term exposure limit
MIT	Contains no substances with occupational exposure limit values nor with short term exposure limit
NaN3	TWA value 0,1 mg/m3 (in EU); STEL: 0,3 mg/m3 (in EU)
NBT	Contains no substances with occupational exposure limit values nor with short term exposure limit

Values according to Directive 98/24/EC + Article 2(3) of Commission Decision 2014/113/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.
STEL: Short Term Exposure Limit; i.e. the acceptable average exposure over a short period of time, usually 15 minutes as long as the time-weighted average is not exceeded.

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				
	STRIP	DIL / BUF	WASH / SOLN / CONC	Ab / AP	SUB
Appearance:	Solid (fibrous sheet); colour: white to yellow	Liquid reagent Colour: yellow	Liquid reagent Colour: colourless	Liquid reagent Colour: red	Liquid reagent Colour: pale yellow
Odour:	None	Negligible	Negligible	Negligible	Negligible
Odour threshold:	N/A	Not given	Not given	Not given	Not given
pH value:	Not given	Not given	Not given	Not given	Not given
Melting point/freezing point:	Decomposes	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:	Yes, if exposed to: flames, sparks, shocks, static discharge, acids	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:	Insoluble in water	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:	185°C	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
Oxidizing properties:	Not given	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

NaN3 (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 liquid reagents.
Oxidizing materials may adversely affect the functionality of cellulose nitrate.

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

a. Acute toxicity

Ingredient	Measured quantity	Value	Species
Cellulose Nitrate	LD_{50} (oral)	3200 mg/kg	Rat
MIT	LD_{50} (oral)	-	-
NaN_3	LD_{50} (oral)	27 mg/kg	Rat
NBT	LD_{50} (oral)	2000 mg/kg	Mouse

LD_{50} test: Lethal dose for 50% of the population of test animals

b. Skin corrosion/irritation
No skin corrosion or irritation known

c. Serious eye damage/irritation
No eye damage or irritation known

d. Respiratory or skin sensitisation
No respiratory or skin sensitisation known

e. Germ cell mutagenicity
No data available

f. Carcinogenicity
No data available

g. Reproductive toxicity
No data available

h. STOT-single exposure
No data available

i. STOT-repeated exposure

Ingredient	STOT-repeated exposure	Comment
Cellulose Nitrate	N/A	-
MIT	N/A	-
NaN_3	May cause damage to brain	N/A, low concentration in mixture (0.1 %)
NBT	N/A	-

j. Aspiration hazard
No data available

12 ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Toxicity for algae	Toxicity for daphnia	Toxicity for fish	Toxicity for microorganisms
Cellulose Nitrate	Acute EC_{50}: 579000 µg/l 96 h Fresh water	-	-	-
MIT	-	-	-	-
NaN_3	EC50=0.35 mg/L 96 h *Pseudokirchneriella subcapitata*	-	LC50=5.46 mg/L 96 h *Pimephalespromelas*	-
NBT	-	-	-	-

LC_{50} 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 litre, or parts per million (ppm), of air or water.

EC_{50} static test: (Effective Concentration 50) Concentration of test substance in dilution water that is calculated to effect 50 percent of a test population during continuous exposure over a specified period of time.

12.2 Persistence and degradability

Ingredient	Measured quantity	Value	Comment
Cellulose Nitrate	No data available	-	-
MIT	No data available	-	-
NaN3	No data available	-	-
NBT	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

This mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Ingredient	Effect
Cellulose Nitrate	None
MIT	Toxic to aquatic life
NaN3	Very toxic to aquatic life with long lasting effects
NBT	No data available

**) The reagents in the kits are mixtures. Due to the very low concentration of toxic substances in the mixture, the handling and use of them 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. Humidify cellulose nitrate before disposal.
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

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.

- ***Commission Regulation (EU) N° 2015/830*** 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° 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.

- ***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

- ***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)

15.2 Chemical safety assessment

No chemical safety assessment has been carried out.

16 OTHER INFORMATION

The present MSDS has been compiled according to the ANNEX II of the **Commission Regulation (EU) 2015/830 of 28 May 2015**.
ANNEX II of Commission Regulation (EU) 2015/830 *replaces*

- Annex II [(1)] of Regulation (EC) No 1907/2006
- Article 59(5) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council (which amends [(1)])
- Commission Regulation (EU) No 453/2010 (which amends [(1)])

Full text of hazard phrases mentioned in this document:

Hazard phrases

Code	Phrase
H228	Flammable solid
H300	Fatal if swallowed
H301	Toxic if swallowed
H302	Harmful if swallowed
H310	Fatal in contact with skin
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
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects

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