



ENA<sup>6</sup> IgG

**SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**1.1. Product Identifier**

Product Name: BlueDot ENA<sup>6</sup> IgG  
Product Code: ENAD-24

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

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

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

D-TEK s.a  
Parc Initialis, rue René Descartes 19  
BE-7000 Mons Belgium  
Tel.: +32 65 841 888  
Fax: +32 65 842 663  
Internet: [www.d-tek.be](http://www.d-tek.be)  
email: [info@d-tek.be](mailto:info@d-tek.be)

**1.4. Emergency telephone number**

D-tek s.a. (only office hours): +32 65 841 888  
Centre Anti-Poisons (BE) 070 245 245  
*Please refer to your local Anti-Poison Centre!*

**SECTION 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 product contains 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.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

**3.1 Substances**

N/A (see hereunder: mixture)

**3.2 Mixtures**

**Abbreviations in alphabetic order:**

AP = Alkaline Phosphatase; BCIP = Bromo-Chloro-Indolyl-Phosphate; BSA = Bovine Serum Albumin; KCl = Potassium Chloride; MgCl<sub>2</sub> = Magnesium Chloride; MIT = MethylIsoThiazolone (preservative); NaCl = Sodium Chloride; NaN<sub>3</sub> = Sodium Azide; NBT = NitroBlue Tetrazolium; TBS = Tris Buffer Saline

Contents	Quantity	Ingredients
Sample Buffer <b>[DIL]</b>	1 vial of 40 mL	H <sub>2</sub> O, TBS, NaCl, Tween, BSA, MIT, dye
Wash Buffer <b>[WASH 10x]</b>	1 vial of 40 mL	H <sub>2</sub> O, TBS, NaCl, Tween, MIT
Conjugate <b>[CONJ IgG]</b>	1 vial of 40 mL	H <sub>2</sub> O, TBS, NaCl, KCl, MgCl <sub>2</sub> , AP-conjugated goat anti-human IgG, MIT, dye
Substrate <b>[SUB]</b>	1 vial of 40 mL	H <sub>2</sub> O, NaN <sub>3</sub> (0.05 %), MgCl <sub>2</sub> , TBS, NBT, BCIP, NBT Stabilizer
Membrane Strips <b>[STRIP]</b>	24 units	Membrane (cellulose nitrate), coated with purified antigens: <b>Sm</b> (purified from bovine thymus), <b>Sm/RNP</b> (purified from bovine thymus), <b>SSA/Ro60kD</b> (60kD, human recombinant), <b>SSB</b> (recombinant, human), <b>Jo-1</b> (recombinant, human) and <b>Scl-70</b> (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.

**Abbreviations and significances:**

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

EINECS: European Inventory of Existing Commercial Chemical Substances

STOT RE: Specific target organ toxicity (repeated exposure)

Information on significance H Phrases: see Section 16

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	Concentration in mixture	Classification (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 <sub>3</sub>	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

**SECTION 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.

**SECTION 5. FIRE-FIGHTING MEASURES**

<b>Flammability:</b>	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.
<b>Extinguishing Media:</b>	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.
<b>Special Fire Fighting Procedures:</b>	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.

**SECTION 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

**SECTION 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

**SECTION 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
NaN <sub>3</sub>	TWA value 0,1 mg/m <sup>3</sup> (in EU); STEL value: 0,3 mg/m <sup>3</sup> (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/m<sup>3</sup>.

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**

<b>Respiratory protection:</b>	None
<b>Gloves:</b>	Laboratory nitrile or latex gloves
<b>Eye protection:</b>	Goggles
<b>Skin protection</b>	Laboratory coat

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

	Kit Reagent				
	STRIP	DIL	WASH 10x	CONJlgG	SUB
<b>Appearance:</b>	Solid (fibrous sheet); colour: white to yellow	Liquid reagent Colour: yellow	Liquid reagent Colour: colourless	Liquid reagent Colour: red	Liquid reagent Colour: pale yellow
<b>Odour:</b>	None	Negligible	Negligible	Negligible	Negligible
<b>Odour threshold:</b>	N/A	Not given	Not given	Not given	Not given
<b>pH value:</b>	Not given	Not given	Not given	Not given	Not given
<b>Melting point/freezing point:</b>	Decomposes	Not given	Not given	Not given	Not given
<b>Initial boiling point and boiling range:</b>	Not given	Not given	Not given	Not given	Not given
<b>Flash point:</b>	N/A	N/A	N/A	N/A	N/A
<b>Evaporation rate:</b>	N/A	N/A	N/A	N/A	N/A
<b>Flammability:</b>	Yes, if exposed to: flames, sparks, shocks, static discharge, acids	N/A	N/A	N/A	N/A
<b>Upper/lower flammability or explosive limits:</b>	Not explosive	Not explosive	Not explosive	Not explosive	Not explosive
<b>Vapour pressure:</b>	Not given	Not given	Not given	Not given	Not given
<b>Vapour density:</b>	Not given	Not given	Not given	Not given	Not given
<b>Relative density:</b>	Not given	Not given	Not given	Not given	Not given
<b>Solubility:</b>	Insoluble in water	Completely soluble	Completely soluble	Completely soluble	Completely soluble
<b>Partition coefficient n-octanol/water:</b>	Not given	Not given	Not given	Not given	Not given
<b>Auto-ignition temperature:</b>	185°C	Not given	Not given	Not given	Not given
<b>Decomposition temperature:</b>	Not given	Not given	Not given	Not given	Not given
<b>Viscosity:</b>	Not given	Not given	Not given	Not given	Not given
<b>Explosive properties:</b>	Not explosive	Not explosive	Not explosive	Not explosive	Not explosive
<b>Oxidizing properties:</b>	Not given	Not given	Not given	Not given	Not given

**9.2 Other information**

N/A

**SECTION 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**

NaN<sub>3</sub> (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).

## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### a. Acute toxicity

Ingredient	Measured quantity	Value	Species
Cellulose Nitrate	LD <sub>50</sub> (oral)	3200 mg/kg	Rat
MIT	LD <sub>50</sub> (oral)	-	-
NaN <sub>3</sub>	LD <sub>50</sub> (oral)	27 mg/kg	Rat
NBT	LD <sub>50</sub> (oral)	2000 mg/kg	Mouse

LD<sub>50</sub> 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 <sub>3</sub>	May cause damage to brain	N/A, low concentration in mixture (0.1 %)
NBT	N/A	-

#### j. Aspiration hazard

No data available

## SECTION 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

Ingredient	Toxicity for algae	Toxicity for daphnia	Toxicity for fish	Toxicity for microorganisms
Cellulose Nitrate	Acute EC <sub>50</sub> : 579000 µg/l Fresh water (exposure 96 hours)	-	-	-
MIT	-	-	-	-
NaN <sub>3</sub>	EC <sub>50</sub> =0.35 mg/L - 96 h - <i>Pseudokirchneriella subcapitata</i>	-	LC <sub>50</sub> =5.46 mg/L - 96 h <i>Pimephalespromelas</i>	-
NBT	-	-	-	-

LC<sub>50</sub> 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). LC<sub>50</sub> is measured in micrograms (or milligrams) of the material per litre, or parts per million (ppm), of air or water.

EC<sub>50</sub> 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	-	-
NaN <sub>3</sub>	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 in pure form*
Cellulose Nitrate	none
MIT	Toxic to aquatic life
NaN <sub>3</sub>	Very toxic to aquatic life with long lasting effects
NBT	No data available

\*) The reagents in D-tek's 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.

## SECTION 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Emptied bottles and vials and used strips may retain product residues: always handle as if they were full.

Humidify cellulose nitrate strips 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.

### Disposal of the packaging

Disposal always according to official regulations: please contact the authority in the matter.

## SECTION 14. TRANSPORT INFORMATION

14.1 to 14.7: N/A: The products are not subject to transport regulations.

## SECTION 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.

#### SECTION 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 <sup>(1)</sup> 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 <sup>(1)</sup>)
- Commission Regulation (EU) No 453/2010 (which amends <sup>(1)</sup>)

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