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Nucleosome IgG

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

1.1. Product Identifier

Product Name: BlueDot Nucleosome IgG

Product Code: NUD-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 antigen Nucleosome.

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
email: 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 product is not classified as dangerous.

2.2 Label elements

According to Regulation (EC) No 1272/2008: 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 product should only be handled by appropriately trained personnel and with the necessary precautions for chemicals.

Abbroviation Substance

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

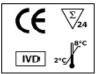
N/A (see hereunder: mixture)

Abbreviation Substance

3.2 Mixtures

Appreviation	Substance		Appreviation	Substance	
AP	Alkaline Phosphatase		MIT	MethylIsoThiazolones (preservative)	
BCIP	Bromo-Chloro-Indolyl-Phosphate		NBT	NitroBlueTetrazolium	
BSA	Bovine Serum Alb	umin	TBS	Tris Buffer Saline	
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Contents	Quantity	Ingredients			
Sample Buffer DIL	1 vial of 40 mL	TBS, Tween 20, BSA, Dye, MIT			
Wash Buffer WASH 10x	1 vial of 40 mL	TBS, Tween 20, MIT			
Conjugate CONJ IgG	1 vial of 40 mL	Goat anti-human IgG/AP, Dye, MIT			
Substrate SUB	1 vial of 40 mL	BCIP, NBT, Sodium Azide			
Membrane Strips STRIP	24 units	Membrane-coated with purified antigens: Nucleosome (purified from bovine thymus chromatin).			





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Hazardous Substances and their concentrations in the mixture

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).

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

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

Name	CAS	EINECS	Concentration mixture	in	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	EINECS Concentration in mixture	in	n 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

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

Information on significance of R and H Phrases: see Section16

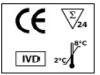
SECTION 4. FIRST AID MEASURES

	SYMPTOMS	FIRST AID
Contact with eyes:	Irritation. Tears	Immediately flush eyes thoroughly with water.
Contact with skin:	Irritation	Immediately wash skin with soap and 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.

SECTION 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	For fires involving this material, do not enter any enclosed or confined fire space without			
Procedures:	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.			





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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 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 limit/range.

7.3 Specific end use(s)

N/A

SECTION 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/m³ (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/m^3 .

8.2 Exposure controls

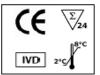
Respiratory protection:	None
Gloves:	Laboratory nitrile or latex gloves
Eye protection:	Goggles
Skin protection	Laboratory coat

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

	Kit Reagent					
	DIL	WASH 10x	[CONJ IgG	SUB		
Appearance:	Liquid reagent Colour: yellow	Liquid reagent Colour: colourless	Liquid reagent Colour: red	Liquid reagent Colour: pale yellow		
Odour:	Negligible	Negligible	Negligible	Negligible		
Odour threshold:	Not given	Not given	Not given	Not given		
pH value:	Not given	Not given	Not given	Not given		
Melting point/freezing point:	Not given	Not given	Not given	Not given		
Initial boiling point and boiling range:	Not given	Not given	Not given	Not given		
Flash point:	N/A	N/A	N/A	N/A		
Evaporation rate:	N/A	N/A	N/A	N/A		
Flammability :	N/A	N/A	N/A	N/A		





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	Kit Reagent			_
	DIL	WASH 10x	CONJIgG	SUB
Upper/lower flammability or explosive limits:	Not explosive	Not explosive	Not explosive	Not explosive
Vapour pressure:	Not given	Not given	Not given	Not given
Vapour density:	Not given	Not given	Not given	Not given
Relative density:	Not given	Not given	Not given	Not given
Solubility:	Completely soluble	Completely soluble	Completely soluble	Completely soluble
Partition coefficient n-octanol/water:	Not given	Not given	Not given	Not given
Auto-ignition temperature :	Not given	Not given	Not given	Not given
Decomposition temperature :	Not given	Not given	Not given	Not given
Viscosity:	Not given	Not given	Not given	Not given
Explosive properties :	Not explosive	Not explosive	Not explosive	Not explosive
Oxidizing properties :	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

Sodium Azide (in $\underline{\text{high}}$ 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 <u>not</u> liberate toxic gas (only carbon dioxide and water vapour).

SECTION 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	

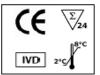
LD₅₀ test: Lethal dose for 50% of the population of test animals

Other health effects

Ingredient	Irritation corrosivity	and	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





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SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Toxicity algae	for Toxicity daphnia	for Toxicity for fish	Toxicity for microorganisms
MIT	-	-	-	-
NBT	-	-	-	-
Sodium Azide	Oncorhyno LC50= 0.7 Lepomis n LC50=5.4		LC50= 0.8 mg/L Oncorhynchus mykiss 96 h LC50= 0.7 mg/L Lepomis macrochirus 96 h LC50=5.46 mg/L Pimephalespromelas 96 h	-

 LC_{50} test: (Lethal Concentration 50) Standard measure of the toxicity of the surrounding medium that will \overline{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	odium 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.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Emptied bottles and vials 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.

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.

- **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.





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- 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.

SECTION 16. OTHER INFORMATION

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

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	

Risk phrases

- F		
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 environment	