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

#### 1.1. **Product Identifier**

Product Name: BlueDiver Dot Connectivitis IgG

Product Code: CTDIV-24

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

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

#### 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 +32 65 842 663 Fax: Internet: www.d-tek.be info@d-tek.be email:

#### 14 **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

#### Classification of the substance or mixture 2.1

According to Regulation (EC) N° 1272/2008 the preparation is not classified as dangerous.

#### 2.2 **Label elements**

According to Regulation (EC) Nº 1272/2008: none

# 2.3

The products / product components contain preservatives which may possess in their given concentration, skinsensitizing 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

# SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 **Substances**

N/A (see hereunder: mixture)

#### 3.2 **Mixtures**

<b>Abbreviation</b>	Substance	Abbreviation	Substance
AP	Alkaline Phosphatase	NBT	NitroBlueTetrazolium
BCIP	Bromo-Chloro-Indolyl-Phosphate	TBS	Tris Buffer Saline
MIT	MethyllsoThiazolone (preservative)		

Contents	Quantity	Ingredients	s		
1. Cartridge	24 units having	g each 7 compa	artments (Position I to VII); sealed, containing:		
Sample Buffer DIL	Position I, 1 x 1,	4 mL (yellow)	TBS, Sodium Chloride, Tween 20, Dye, MIT, antifoam emulsion		
Wash Buffer WASH 10x	Position II, III, in mL (colourless)	IV, VI, 1 x 1,4	TBS, Sodium Chloride, Tween 20, MIT, antifoam emulsion		
Conjugate CONJ IgG	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)		( 1,4 mL (pale	TBS, Magnesium Chloride, BCIP, NBT, NBT Stabilizer, Sodium Azide, antifoam emulsion		
2. Strips	3 x 8 units on	plastic support	s, breakable individually; sealed		
Membrane Strip	10 dots on each 1 positive contro 8 antigens 1 negative contr	ol (C+)	Membrane-coated with purified antigens:  Nucleosome (purified from bovine thymus chromatin), Histones (mixture of H1, H2a, H2b, H3 and H4, purified from bovine thymus), Sm (purified from bovine thymus), Sm/RNP (purified from bovine thymus), SSA/Ro60kD (recombinant, human), SSB (recombinant, human), Jo-1 (recombinant, human) and ScI-70 (recombinant, human)		





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

Name	CAS	EINECS	Concentration mixture	in	Classification ( according to Re	in concentrated form) egulation
					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: corrosive N:dangerous for the environment T:toxic T+:very toxic Xn:harmful

Information on significance of R and H Phrases: see Section16

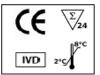
# SECTION 4. FIRST AID MEASURES

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

	<u> </u>			
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 (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
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/m³.

# 8.2 Exposure controls

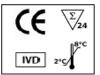
Respiratory protection:	None
Gloves:	Laboratory nitrile or latex gloves
Eye protection:	Goggles
Skin protection	Laboratory coat

# SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

# 9.1 Information on basic physical and chemical properties

	Kit Reagent			
	DIL	WASH 10x	CONJIgG	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
Upper/lower flammability or explosive limits:	Not explosive	Not explosive	Not explosive	Not explosive





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	Kit Reagent			
	DIL	WASH 10x	CONJIIgG	SUB
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

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 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 <sub>50</sub> (oral)	-	-
NBT	LD <sub>50</sub> (oral)	2000 mg/kg	Mouse
Sodium Azide	LD <sub>50</sub> (oral)	27 mg/kg	Rat

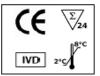
LD<sub>50</sub> test: Lethal dose for 50% of the population of test animals

# 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	-	-	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 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.

#### SECTION 13. DISPOSAL CONSIDERATIONS

# 13.1 Waste treatment methods

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

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

### **SECTION 14. TRANSPORT INFORMATION**

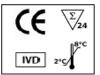
**14.1 to 14.7**: N/A: The products are not subject to transport regulations.

# 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.

- 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





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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.

## **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

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