

Polymyositis/Scleroderma¹² IgG

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product Identifier

Product Name: BlueDiver Dot Polymyositis/Scleroderma¹² IgG
Product Code: PMS12DIV-24
UFI: N/A

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

Immunodot kit (professional IVD use only, automated on the *BlueDiver Instrument*) for the detection of IgG antibodies to the antigens Jo-1, PL-7, PL-12, EJ, SRP-54, Mi-2, MDA-5, TIF1- γ , Ku, PM-Scl 100, Scl-70 and SSA/Ro 52kD 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
Website: www.d-tek.be
email: info@d-tek.be

1.4. Emergency telephone number

Please refer to your local Anti-Poison Centre or contact the European Chemicals Agency (ECHA): website <https://poisoncentres.echa.europa.eu/appointed-bodies>; tel: +358-9-686180.

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 mixture is for professional use only and does not come into contact with the patient. The professional user has to observe the precautions for safe handling given in 7.1. The criteria for persistent, bioaccumulative and toxic or very persistent and very bioaccumulative effects do not apply. Neither does the mixture have endocrine disrupting properties.

The 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.

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; MgCl₂ = Magnesium Chloride; MIT = MethylIsoThiazolone (preservative); NaCl = Sodium Chloride; NaN₃ = Sodium Azide; NBT = NitroBlue Tetrazolium; TBS = Tris Buffer Saline

Contents	Quantity	Ingredients
1. Cartridge	24 units having each 7 compartments (Position I to VII); sealed, containing:	
Sample Buffer [DIL]	Position I, 1 x 1,4 mL (yellow)	H ₂ O, TBS, NaCl, Tween, BSA, MIT, Dye, antifoam emulsion
Wash Buffer [WASH]	Position II, III, IV, VI, 1 x 1,4 mL (colourless)	H ₂ O, TBS, NaCl, Tween, MIT, antifoam emulsion
Conjugate [CONJ]IgG	Position V, 1 x 1,4 mL (red)	H ₂ O, TBS, NaCl, KCl, MgCl ₂ , AP-conjugated goat anti-human IgG, MIT, Dye, antifoam emulsion
Substrate [SUB]	Position VII, 1 x 1,4 mL (pale yellow)	H ₂ O, NaN ₃ (0.05 %), MgCl ₂ , TBS, NBT, BCIP, NBT Stabilizer
2. Strips	3 x 8 units on plastic supports, breakable individually; sealed	
Membrane Strip [STRIP]	14 dots on each: 1 positive control (C+) 12 antigens 1 negative control (C-)	Membrane (cellulose nitrate), coated with the antigens: Jo-1 (recombinant, human), PL-7 (recombinant, human), PL-12 (recombinant, human), EJ (recombinant, human), SRP-54 (recombinant, human), Mi-2 (recombinant, human), MDA-5 (recombinant, human), TIF1-γ (recombinant, human), Ku (recombinant, human), PM-Scl 100 (recombinant, human), Scl-70 (recombinant, human) and SSA/Ro 52kD (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. 2 H330 Acute Tox. 2 H310 Acute Tox. 3 H301 Skin Corr. 1 C H314; C ≥ 0,6% Eye Dam. 1 H318; C ≥ 0,6% Skin Sens. 1 A H317; C ≥ 0,0015% A Aquatic Acute 1 H400 Aquatic Chronic 1 H410

Annex to Commission Regulation (EU) 2018/1480; Index Number: 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

SECTION 4. First aid measures

4.1 Description of first aid measures

Contact with eyes: Immediately flush eyes thoroughly with water
Contact with skin: Immediately wash skin with soap and large volumes of water
Ingestion: If swallowed, wash out mouth with water (provided the person is conscious)

4.2 Most important symptoms and effects, both acute and delayed

Contact with eyes: Irritation, tears
Contact with skin: Irritation
Ingestion: Nausea

4.3 Indication of any immediate medical attention and special treatment needed

If person unconscious or symptoms do not fade, seek medical advice by showing this document.
In any case, never give anything by mouth to an unconscious person and never try to make an unconscious person vomit.

SECTION 5. Firefighting measures

5.1 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.

5.2 Special hazards arising from the substance or mixture

None

5.3 Advice for firefighters

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, protective equipment and emergency procedures

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 ₃	TWA value 0,1 mg/m ³ (in EU); STEL: 0,3 mg/m ³ (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

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

	Kit Reagent				
	STRIP	DIL	WASH	CONJ IgG	SUB
a) Physical state	Solid (fibrous sheet)	Liquid reagent	Liquid reagent	Liquid reagent	Liquid reagent
b) Colour	white to yellow	yellow	colourless	red	pale yellow
c) Odour:	None	Negligible	Negligible	Negligible	Negligible
d) Melting point/freezing point:	Decomposes	Not given	Not given	Not given	Not given
e) Boiling point or initial boiling point and boiling range	Not given	Not given	Not given	Not given	Not given
f) Flammability:	Yes, if exposed to: flames, sparks, shocks, static discharge, acids	N/A	N/A	N/A	N/A
g) Lower and upper explosion limit	N/A	Not explosive	Not explosive	Not explosive	Not explosive
h) Flash point:	N/A	N/A	N/A	N/A	N/A
i) Auto-ignition temperature:	185°C	Not given	Not given	Not given	Not given
j) Decomposition temperature:	Not given	Not given	Not given	Not given	Not given
k) pH value:	Not given	Not given	Not given	Not given	Not given
l) Kinematic viscosity:	Not given	Not given	Not given	Not given	Not given
m) Solubility:	Insoluble in water	Completely soluble	Completely soluble	Completely soluble	Completely soluble
n) Partition coefficient n-octanol/water (log value):	Not given	Not given	Not given	Not given	Not given
o) Vapour pressure:	Not given	Not given	Not given	Not given	Not given
p) Density and/or relative density	Not given	Not given	Not given	Not given	Not given
q) Relative vapour density:	Not given	Not given	Not given	Not given	Not given
r) Particle characteristics	N/A	N/A	N/A	N/A	N/A

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

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).

SECTION 11. Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

LD₅₀ 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

11.2 Information on other hazards

N/A (no endocrine disrupting properties)

SECTION 12. Ecological information

12.1 Toxicity

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

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.

EC₅₀ 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 ₃	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 Endocrine disrupting properties

This mixture contains no components considered to have endocrine disrupting properties.

12.7 Other adverse effects

Ingredient	Effect in pure form*
Cellulose Nitrate	none
MIT	Toxic to aquatic life
NaN ₃	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 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.

Disposal of the packaging

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

SECTION 14. Transport information

14.1 UN Number or ID number

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

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

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

14.6 Special precautions for user

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

14.7 Maritime transport in bulk according to IMO instruments

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) 2020/878** amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- **Commission Regulation (EU) 2018/1881(2)** amending Annexes I, III and VI to XII to Regulation (EC) No 1907/2006
- **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.
- **The Globally Harmonised System of Classification and Labelling of Chemicals (GHS)** developed in the framework of the United Nations, setting out internationally harmonised criteria for the classification and labelling of chemicals and rules on safety data sheets
- **COM(2018) 734 - COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS** towards a comprehensive European Union framework on endocrine disruptors
- **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 **Commission Regulation (EU) 2020/878 of 18 June 2020**. REGULATION (EU) 2020/878 replaces

- Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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
H318	Causes serious eye damage
H330	Fatal if inhaled
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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