

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY**1.1 Product identifier**

Product Name: DIASpot Polymyositis/Scleroderma⁸ IgG

Catalog #: KAPDTPMS8

Kit Components: Diluent Buffer
Wash Buffer
Conjugate
Substrate
Dot Strips
Incubation Trays

1.2 Intended Use

Immunodot kit (professional IVD use only) for the detection in human serum of IgG antibodies to the antigens Jo-1, PL-7, PL-12, SRP, Mi-2, Ku, PM-Scl 100 and Scl-70.

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 product is not classified as dangerous.

2.2 Label elements

According to *Regulation (EC) N° 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.

3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

N/A (see hereunder: mixture)

3.2 Mixtures

| Abbreviation | Substance | Abbreviation | Substance |
|-------------------|--------------------------------|------------------|----------------------|
| AP | Alkaline Phosphatase | MIT | MethylIsoThiazolones |
| BCIP | Bromo-Chloro-Indolyl-Phosphate | NBT | NitroBlueTetrazolium |
| BSA | Bovine Serum Albumin | TBS | Tris Buffer Saline |
| KCl | Potassium Chloride | NaCl | Sodium Chloride |
| MgCl ₂ | Magnesium Chloride | NaN ₃ | Sodium Azide |

| Contents | Quantity | Ingredients |
|-------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sample Buffer DIL BUF | 1 vial of 40 mL | H ₂ O, TBS, NaCl, Tween, BSA, MIT, dye |
| Wash Buffer WASH SOLN CONC | 1 vial of 40 mL | H ₂ O, TBS, NaCl, Tween 20, MIT |
| Conjugate Ab AP | 1 vial of 40 mL | H ₂ O, TBS, NaCl, KCl, MgCl ₂ , AP-conjugated goat anti-human IgG, MIT, Dye |
| Substrate SUB | 1 vial of 40 mL | H ₂ O, NaN ₃ (0.05%), MgCl ₂ , TBS, NBT, BCIP, NBT Stabilizer |
| Membrane Strips STRIP | 24 units | Membrane (cellulose nitrate), coated with purified antigens: Jo-1 (recombinant, human), PL-7 (recombinant, human), PL-12 (recombinant, human), SRP (recombinant, human), Mi-2 (recombinant, human), Ku (recombinant, human), PM-Scl 100 (recombinant, human) and Scl-70 recombinant, human). |

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).

| 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 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 |

Abbreviations and significances:

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

EINECS: European Inventory of Existing Commercial Chemical Substances

Information on significance of R and H Phrases: see Section 16

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 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

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 value: 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 |

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| | Kit Reagent | | | | |
|------------------------------------------------------|------------------------------------------------------------------------|----------------------------------|--------------------------------------|-------------------------------|---------------------------------------|
| | STRIP | DIL | WASH 10x | CONJ/IgG | 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

Sodium Azide (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 not liberate toxic gas (only carbon dioxide and water vapour).

11 TOXICOLOGICAL INFORMATION**11.1 Information on toxicological effects****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

Skin corrosion/irritation

No skin corrosion or irritation known

Serious eye damage/irritation

No eye damage or irritation known

Respiratory or skin sensitisation

No respiratory or skin sensitisation known

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

STOT-single exposure

No data available

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 | - |

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 Fresh water (exposure 96 hours) | - | - | - |
| MIT | - | - | - | - |
| NaN ₃ | EC50=0.35 mg/L - 96 h <i>Pseudokirchneriella subcapitata</i> | - | LC50=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 litre, 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 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 Diasource 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 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.

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

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

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 |

MSDS established : 2023-04-12

Revision number : 3