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1. Name of the preparation and company

**1.1. Product identity**

**Trade name:** DotDiver Myositis 12, 24 x 12 determinations

**Article no.:** 5093

**1.2. Using**

The DotDiver Myositis 12 is used for the separate qualitative determination of autoantibodies to Jo-1, PL-7, PL-12, EJ, SRP, Mi-2, MDA-5, TIF1- $\gamma$ , SSA/Ro52kD, SAE1, SAE2 and NXP-2 in human serum or plasma for the differential diagnosis of autoimmune myositis diseases. Processing of the test is done using the DotDiver instrument.

**1.3. Manufacturer**

GA Generic Assays GmbH  
Ludwig-Erhard- Ring 3  
15827 Dahlewitz  
Phone +49-(0)33708-9286-0  
Fax: +49-(0)33708-9286-50  
Internet: [www.genericassays.com](http://www.genericassays.com)  
E-mail: [info@genericassays.com](mailto:info@genericassays.com)

**1.4. Emergency number**

GA Generic Assays GmbH Tel.: +49-(0) 33708 9286-0

**2. Hazards**

**2.1. Classification of the mixture**

The products / product components are **classified as non hazardous** according to EU regulation 1272/2008/EG.

**2.2. Labeling elements**

According to 1272/2008/EG: none

**2.3. Other hazards**

The products / product components contain preservatives which may at their given concentration possessing sensitizing and slightly polluting properties. As always special dangers posed by chemicals, the products / product components should be handled only by appropriately trained personnel and with the necessary for chemicals.

Results of PBT / vPvB assessment not applicable

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### **3. Composition / Information on ingredients**

#### **3.1. Description of ingredients**

<b>Component</b>	<b>Ingredients</b>	<b>Preservative</b>
Cartridge: Sample buffer	H <sub>2</sub> O • TBS • NaCl • Tween, Dye • Antifoam emulsion	0.0015% Methylisothiazolone
Wash buffer	H <sub>2</sub> O • TBS • NaCl • Tween • Dye Antifoam emulsion	0.0015% Methylisothiazolone
Conjugate	AP-conjugated goat anti-human IgG • Stabilizer Dye • Antifoam emulsion	0.0015% Methylisothiazolone
Substrate	NBT / BCIP, Antifoam emulsion	0.05% Sodium azide
Membrane Strips	Antigens: Jo-1, PL-7, PL-12, EJ, SRP, Mi-2, MDA-5, TIF1-γ, SSA/Ro52kD, SAE1, SAE2 and NXP-2	

#### **3.2. Hazardous Components and their Concentrations**

<b>CAS No.</b>	<b>EINECS No.</b>	<b>Ingredient</b>	<b>Percent</b>	<b>Classification (in conc. Form) to 1272/2008/EG</b>
26628-22-8	247-852-1	Sodium azide	< 0.1	Acute tox. 2, H300 Aquatic acute 1, H400 Aquat. Chronic 1, H410
2682-20-4	220-239-6	Methylisothiazolone	0.0015	Toxic 3.1; H302, 314, 317 Aquatic acute; H400

The full wording of the listed hazard warnings is given in section 16.

### **4. First aid measures**

#### **4.1. Description of first aid measures**

Due to the very low concentrations of the hazardous ingredients in the product/components, consultation of a doctor is not necessary.

In cases of contact with skin, wash with copious amounts of water.

In cases of contact with eyes, rinse out for several minutes with water, with eyelids open.

In cases of swallowing, rinse out and drink copious amounts of water.

#### **4.2. Important symptoms and effects**

There are no known acute or delayed onset symptoms and effects.

#### **4.3. Indications for immediate medical assistance and special handling**

Where necessary consult an ophthalmologist.

Wash contaminated clothing before reuse.

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### **5. Fire-fighting measures**

#### **5.1. Extinguishers**

Extinguishers indicated: water spray, foam, powder.

#### **5.2. Special hazards arising from the contents**

With fire, sodium azide can release poisonous fumes.

#### **5.3. Notes on firefighting**

Surround the fire with appropriate extinguishing material.

If necessary use breathing apparatus and protective clothing for firefighting.

### **6. Accidental release measures**

#### **6.1. Personal precautions**

Observe the safety regulations of the laboratory.

To minimize the risk of contact with the skin and eyes, wear appropriate protective clothing. Do not swallow, do not pipette by mouth.

#### **6.2. Environmental precautions**

Do not release into drains/surface water/ground water.

#### **6.3. Methods and materials for containment and cleaning**

Contain spills with absorbent material, and dispose of appropriately. Following complete removal of the material, clean the affected area thoroughly.

#### **6.4. Reference to other sections**

Information on appropriate protective clothing can be found in section 8.2.

For disposal, consult section 13.

### **7. Handling and Storage**

#### **7.1. Protective measures for safe handling**

Apart from the usual laboratory safety regulations, no particular protective measures are required.

Information on required protective clothing can be found in section 8.2.

#### **7.2. Conditions for safe storage, including any incompatibilities**

When well sealed according to instructions on the product components, storage at 2 - 8°C or -20°C

#### **7.3. Specific end-uses**

No further relevant information available.

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### **8. Exposure controls / personal protection**

#### **8.1. Parameters/exposure values to be observed**

CAS No.	Ingredient	MAK or AGW (from TRGS 900)
2682-20-4	Methylisothiazolone	no data available
26628-22-8	Sodium azide	0.2 mg/m <sup>3</sup>

With appropriate use of the pack/pack contents, no air pollution is expected.

#### **8.2. Limitations and monitoring of exposure**

<i>Respiratory protection:</i>	Not required
<i>Gloves:</i>	Nitrile or natural latex laboratory gloves
<i>Eye protection:</i>	Safety goggles
<i>Bodily protection:</i>	Appropriate laboratory wear

### **9. Physical and chemical properties**

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

*Form:* liquid reagents  
*Colour:* colorless (Wash), yellow (Diluent), red (Conjugate), colorless (Substrate)  
*Smell:* negligible  
*Melting point / melting range / boiling point / boiling range / density:* not determined  
*Flash point:* not applicable  
*Risk of explosion:* no risk of explosion

#### **9.2. Other properties**

Solubility in / miscibility with water: complete

### **10. Stability and reactivity**

#### **10.1. Reactivity**

There are no chemical reactive properties of the product / product components

#### **10.2. Chemical stability**

Within the stated storage temperatures and expiry dates, the product / components are chemically stable.

#### **10.3. Possible hazardous reactions**

In high concentrations sodium azide and heavy metals, such as copper and lead, can form explosive complexes.

#### **10.4. Conditions to be avoided**

Strong light sources can negatively influence the functional ability of the conjugate.

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### 10.5. Incompatible materials

Acids, alkalis and solvents can negatively influence the functional ability of the product / components.

### 10.6. Hazardous decomposition products

Within the stated storage and handling conditions, the product / components product no known hazardous decomposition products.

## 11. Toxicological information

### 11.1. Information on toxicological effects

#### Acute Toxicity

Ingredient	Measurant	Value	Species
Sodium azide	LD50 (oral)	27 mg/kg	Rat
Methylisothiazolone	no data available		

#### Other health effects

Ingredient	Irritation and corrosion	Sensitization	CMR Effect
Sodium azide	No data available	No data available	no data available
Methylisothiazolone	No data available		

## 12. Ecological information

### 12.1. Toxicity

Ingredient	Measurand	Value	Species
Sodium azide	LC50	0.68 mg/l	Sun perch
Sodium azide	EC50	4.2 mg/l	Daphnia pulex
Methylisothiazolone	no data available		

### 12.2. Persistence and biodegradability

Ingredient	Measurand	Value	Remarks
Sodium azide	No data available		
Methylisothiazolone	No data available		

### 12.3. Bioaccumulation potential

No data available

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### **12.4. Mobility in soil**

No data available.

### **12.5. Results of PBT and vPvB analyses**

No data available.

### **12.6. Other harmful effects**

Ingredient	Type of effect
Sodium azide	very poisonous to water organisms

Due to the very low concentration of hazardous ingredients in the product / components, no ecological problems are expected arising from their use.

## **13. Disposal considerations**

### **13.1. Disposal methods**

#### **Product components**

May not be disposed of with household waste.

Residues of chemical preparations are usually classed as waste which must be disposed of according to the rules issued by the country and government. Information on the disposal of hazardous waste can be given by the local authorities (agency or authorized waste disposal contractor).

Radioactive material is to be disposed of in special waste containers suited to this purpose.

#### **Packaging**

Disposal according to official regulations.

Contaminated packaging should be treated as per the product.

Non-contaminated packaging can be handled as household waste and be recycled, when regulations do not state otherwise.

## **14. Transport information**

This product has no transport regulations

### **14.1. UN number**

Not applicable

### **14.2. Transport hazard class**

Not applicable

### **14.3. Packaging group**

Not applicable

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### **14.4. Environmental hazard**

Not applicable

### **14.5. Special precautions for users**

Not applicable

### **14.6. Mass transport in accordance with appendix II MARPOL agreements 73/78 and IBC code**

Not applicable.

## **15. Regulatory information**

This safety data sheet fulfils the requirements of regulation 1907/2006/EG on the registration, evaluation, authorization and restriction of chemicals, ( REACH ), and the EU regulation 1272/2008/EG on the classification, labeling and packaging of chemicals and mixtures, as well as the regulation (EU) 830/2015 on the production of safety data sheets.

### **15.1. Safety, health and environmental regulations/ regulations specific to this substance or mixture**

When handling the product, the current regulations for handling potentially infectious human sample material should be observed.

Product classification to 1272/2008/EG: none

### **15.2 Chemical safety assessment**

A chemical safety assessment has not been performed.

## **16. Other information**

*Full text of risk phrases listed in section 3.2.*

H300	Life-threatening if swallowed
H302	Harmful to health if swallowed
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H400	Very poisonous to water organisms
H410	Very poisonous to water organisms with long-term effects

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### Abbreviations and acronyms

AGW	Arbeitsplatzgrenzwert (workplace limit)
AP	Alkaline Phosphatase
BCIP	Bromo-Chloro-Indolyl-Phosphate
BSA	Bovine serum albumin
CAS	Chemical Abstract Service (division of the American Chemical Society)
CLP	Regulation of Classification, Labelling, and Packaging of Substances and Mixtures
CMR	cancerogenic, mutagenic or reprotoxic
EC50	Effective concentration for 50 % of subjects
EINECS	European Inventory of Existing Commercial Chemical Substances
GHS	Globally Harmonized System of Classification and Labeling of Substances
IBC-Code	International Code for the Construction and Equipment of Ships carrying dangerous Chemicals in Bulk
IARC	International Agency for Research on Cancer
LD50	Lethal dose for 50 % of subjects
LC50	Lethal concentration for 50 % of subjects
MAK	Maximale Arbeitsplatzkonzentration (maximum workplace concentration)
MARPOL	International Convention for the Prevention of Pollution from Ships
MIT	Methylisothiazolone
NBT	Nitrotetrazolium-Chlorideblue
OECD	Organization for Economic Co-operation and Development
PBT/vPvB	Persistent, bioaccumulative, and toxic substances / very persistent and very bioaccumulative substances
REACH	Registration, Evaluation, and Authorisation of Chemicals
TRGS	Technische Regeln für Gefahrstoffe (technical regulations for hazardous chemicals)
TBS	Tris buffered saline
USDA	US Department of Agriculture

The information given is based on our most current knowledge. It is intended to describe our products in terms of safety requirements, and should be seen by users as a guide. It does not form a guarantee of any specific product features, and does not constitute a legal relationship or state liability for damages which may arise from handling or having contact with this product /product components.