

Document No.:

MP-MSDS-3803-E-v03-20-02-05

Safety Data Sheet

According to VO (EU) No.830/2015



1. Identification of the substance and of the Company

1.1. Product Identity

Trade name: Medizym® anti-IA2, 96 determinations

REF No.: 3803

1.2. Intended use

Enzyme immunoassay for the determination of autoantibodies to Protein Tyrosine Phosphatase IA2 in human serum.

1.3. Manufacturer

MEDIPAN GMBH
Ludwig-Erhard- Ring 3
15827 Dahlewitz
Tel: 0049 33708 44 17-0
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1.4. Emergency number

MEDIPAN GMBH Phone: +49 033708 44 17-0

2. Hazard identification

2.1. Classification of the contents

The product / product components are, in accordance to EU Regulation EG Nr.1272/2008 classified as **non -hazardous.**


2.2. Identification elements

According 1272/2008/EG: none

2.3. Other hazards

The product/product components contain preservatives, which in the present concentrations can cause skin sensitization and weak water pollution. As there are always certain dangers associated with chemicals, the product /product components should only be handled by appropriately trained persons, using proper chemical safety precautions.

Results of the PBT/ vPvB-Evaluation: not applicable

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3. Composition / Information on ingredients

3.1. Description of ingredients

Component	Ingredients	Preservative
Microtiter plate	Coated with recombinant human IA2	
Concentrated wash buffer	TRIS, NaCl, Tween 20	0.09% Sodium azide
Streptavidin-peroxidase (SA-POD)	Streptavidin-peroxidase	0.09% Sodium azide
Diluent for SA-POD	TRIS, NaCl, BSA	0.1% Chloroacetamide 0.02% N-Methylisothiazolone
Substrate (TMB)	3.3'5.,5'- Tetramethylbenzidine	0.09% Sodium azide
Stop solution	0.25 M sulfuric acid	
IA2-Biotin	Biotinylated IA2	0.02% N-Methylisothiazolone
Diluent for IA2-Biotin	TRIS, NaCl, BSA	0.09% Sodium azide
Reaction Enhancer	TRIS, NaCl, BSA	0.02% N-Methylisothiazolone
Calibrators and controls	Diluted human serum	0.09% Sodium azide

3.2. Hazardous components and their concentrations

CAS No.	EINECS No.	Ingredient	Percentage	Classification (in conc. Form) to 1272/2008/EG
2682-20-4	220-239-6	N-Methylisothiazolone	0.02	Acute tox. 3, H330, 311, 301 Skin corr. 1B, H314, Skin sens. 1, H317 Aquatic chronic 1, H410
79-07-2	201-174-2	Chloroacetamide	0.1	Acute tox. 3, H301 Skin sens. 1, H317
26628-22-8	247-852-1	Sodium azide	0.09	Acute tox. 2, H300, EUH032 Aquatic acute 1, H400 Aquat. Chronic 1, H410
77-86-1	201-064-4	Tris(hydroxymethyl-)aminomethan (TRIS)	<1	Skin irrit. 2, H315 Eye irrit. 2, H319
7664-93-9	231-639-5	Sulfuric acid	0.25M	Acute tox. 2, H290

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.

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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 treatment

Where necessary consult an ophthalmologist.
Wash contaminated clothing before reuse.

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 fire -fighting

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 / 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.

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7.2. Conditions for safe storage including any incompatibilities

Keep containers tightly closed. Store in a dry place in the box supplied at a temperature between +2 and +8 °C.

7.3. Specificity and use

No further relevant information available.

8. Exposure controls / personal protection

8.1. Parameters/exposure values to be observed

CAS No.	Ingredient	MAK or AGW (from TRGS 900)
26628-22-8	Sodium azide	0.2 mg/m ³
2682-20-4	N-Methylisothiazolone	1.5 mg/m ³
7664-93-9	Sulfuric acid	1 mg/m ³

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

8.2. Limitations and monitoring of exposure

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

Handling of all components has to be done in accordance with Good Laboratory Practice (GLP) regulations.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Kit component	Appearance	Odor	pH	Solubility
Coated wells	Colorless	none	N/A	N/A
IA2-Biotin	White solid	none	N/A	In water
Reconstitution Buffer for IA2- Biotin	Pink liquid	none	~8.0	N/A
Streptavidin Peroxidase (SA-POD)	Pale brown/yellow liquid	none	N/A	N/A
Diluent for SA-POD	Colorless liquid	none	~7.5	N/A
Peroxidase Substrate (TMB)	Colorless to light blue liquid	none	N/A	N/A
Stop Solution	Colorless liquid	none	<1	N/A
Concentrated Wash Solution	Colorless liquid	none	~7.6	N/A
Calibrators and Controls	Pale Yellow/brown liquid	none	N/A	N/A

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9.2. Other properties

Solubility in / miscibility with water: complete

10. Stability and reactivity

10.1. Reactivity

Data is not available on the reactivity of individual kit components but is given, where available, on substances listed in subsection 3.2.

Sulfuric acid is a strong oxidizing agent and has a corrosive effect. There is no data available on the other substances.

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 can form explosive complexes with heavy metals, such as copper and lead.

10.4. Conditions to be avoided

Peroxidase substrate (TMB) is light sensitive and therefore the bottle should be kept tightly closed when Not in use and stored in a dark place.

10.5. Incompatible materials

Acids, alkalis and solvents can negatively influence the functional ability of the conjugate.

10.6. Hazardous decomposition products

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

11. Toxicological information

11.1. Information on toxicological effects

Acute Toxicity

Ingredient	Measurand	Value	Species
Sodium azide	LD ₅₀ (oral)	27 mg/kg	rat
TRIS	LD ₅₀ (oral)	5900 mg/kg	rat
N-Methylisothiazolone	LD ₅₀ (oral)	2838 mg/kg	rat
N-Methylisothiazolone	LD ₅₀ (dermal)	>5000 mg/kg	rabbit
Chloroacetamide	LD ₅₀ (oral)	138 mg/kg	rat
Sulfuric acid	LD ₅₀	2140 mg/kg	rat

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Other health effects

Ingredient	Irritation and corrosion	Sensitizing	CMR effect
N-Methylisothiazolone	skin (rabbit)	yes (guinea pig)	none
TRIS	skin, mucosa, eye	none	no data available
Sodium azide	no data available	no data available	no data available
Sulfuric acid	no data available	no data available	no data available

12. Ecological information

12.1. Toxicity

Ingredient	Measurand	Value	Spezies
Sodium azide	LD ₅₀	0.68 mg/l	Sun perch
Sodium azide	EC ₅₀	4.2 mg/l	Invertebrate (Daphnia pulex)
TRIS	no data available		
N-Methylisothiazolone	LC ₅₀	4,77 mg/l/96h	Rainbow trout
N-Methylisothiazolone	EC ₅₀	0,85 mg/l/48h	Daphnia magna
N-Methylisothiazolone	EC ₅₀	0,22 mg/l	alga (Selenastrum capricornutum)
Sulfuric acid	no data available		

12.2. Persistence and biodegradability

Ingredient	Measurand	Value	Remarks
Sodium azide	no data available		
N-Methylisothiazolone	OECD guideline 301B or equivalent biodegradable	0,32 %	not easily
N-Methylisothiazolone	Sludge Respiration Inhibition (EC ₅₀)	41 mg/l	active substance
Sulfuric acid	LD ₅₀	10mg /L/96h	toxic to aquatic organisms due to pH shift

12.3. Bioaccumulation potential

No data available.

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.

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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).

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. Proper UN shipping designation

Not applicable.

14.3. Transport hazard class

Not applicable.

14.4. Packaging group

Not applicable.

14.5. Environmental hazard

Not applicable.

14.6. Special precautions for users

Not applicable.

14.7. 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.

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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 section 3.2., listed risk phrases

EUH032	Produces very poisonous gases on contact with acids.
H290	May be corrosive to metals
H300	Fatal if swallowed
H301	Toxic if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H330	Fatal if inhaled
H400	Very poisonous for water organisms
H410	Very poisonous for water organisms with long-term effect

Abbreviations and acronyms

AGW	Workplace limit
CAS	Chemical Abstract Service (division of American Chemical Society)
CLP	Regulation of Classification, Labelling, and Packaging of Substances and Mixtures
CMR	Carcinogenic, 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 Labelling 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	Maximum workplace concentration
MARPOL	International Convention for the Prevention of Pollution from Ships
OEDC	Organisation 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
TGRS	Technische Regeln für Gefahrstoffe (technical regulations for hazardous chemicals)
USDA	US Department of Agriculture

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