



Mascia Brunelli S.p.A.

VQ81706 – MALARIA MBPan

Revision nr. 4

Dated 23/04/2024

Printed on 23/04/2024

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Replaced revision: 3 (Printed on: 03/05/2018)

SAFETY DATA SHEET

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

1.1 Product identifiers

Code: **VQ81706**
Product name: **MALARIA MBPan**

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

Identified use: **Immunochromatographic rapid test on membrane for the detection of Malaria P.f/P.v/P.o/P.m in human serum, plasma and whole blood specimen**

Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name: **Mascia Brunelli S.p.A.**
Full address: **Viale Monza, 272**
District and Country: **20128 Milano (Milano)**
Italia

Tel. **0039 02 252091**

e-mail address of the competent person,
responsible for the Safety Data Sheet: **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to:
NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as not hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --


2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

SECTION 3: Composition/information on ingredients

3.1 Substances

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Irrilevant.

3.2 Mixtures (Extraction buffer-Diluent)

The product consist of Individually sealed pouch and Extraction Buffer.

Note: The strip is composed of nitrocellulose membrane, vinyl matte adhesive, fiber absorbent pad, fiber sample pad, fiber conjugate pad. The nitrocellulose membrane and the fiber conjugate pad contain dried biological substances preserved by Proclin-300. The identity of each biological substance is confidential.

Identification	x = Conc. %	Classification 1272/2008 (CLP)
Mixture of 5-chloro-2-methyl-4-isotiazolin-3-one and 2-methyl-2H-isotiazol-3-one (3:1) *		
CAS 55965-84-9	x < 0,0015	Acute Tox. 3, H301
EC 911-418-6		Acute Tox. 2, H310+H330
REACH – No.: -		Skin Corr. 1C, H314
INDEX: -		Skin Sens 1A, H317
		Eye Dam. 1, H318
		Acute Aquatic 1, H400 Factor M=100
		Chronic Aquatic 1, H410 Factor M=100

Sodium azide		
CAS 26628-22-8	x < 0,09%	Acute Tox 2, H300
EC 247-852-1		Acute Tox 1, H310
REACH – No.: 01-2119457019-37-XXXX		Acute Tox 2 , H330
		STOT RE 2, H373
INDEX 011-004-00-7		Acute Aquatic 1, H400
		Chronic Aquatic 1, H410
		Acute Tox. Factor M=1
		Chronic Tox. Factor M=1
		ATE oral = 27,0 mg/kg
		ATE dermal > 20,0 mg/kg
		ATE inhal > 0,5 mg/l/4 h

* Specific concentration limits – CAS 55965-84-9:

Eye Dam. 1; H318: C ≥ 0,6%

Eye Irrit. 2; H319: 0,06% ≤ C < 0,6%

Skin Corr. 1C; H314: C ≥ 0,6%

Skin Irrit. 2; H315 : 0,06% ≤ C < 0,6%

Skin Sens. 1A; H317: C ≥ 0,0015%

All the biological substances are derived from in vitro culture system or animal materials which are free of known-pathogens for human. Thus, no bio-hazardous can be claimed in the product.

Occupational limits are listed in section 8 if these are available. See full text of H-phrases in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: Inhalation of any component in this kit is unlikely. If a component of this kit is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.

Direct skin contact: Normally no hazard. In case of contact wash of with soap and water. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fiber conjugate pad are very unlikely to be hazardous by skin contact but clean the skin after use is advisable.

Direct contact with eyes: The test device is very unlikely to be contacted by eye, however, contact physician should a contact occur. In case of contact with the Sample Diluent, immediately flush eyes with plenty of water for several minutes. Cold water may be used. Get medical attention if irritation persist.

Ingestion: Rinse mouth with water and spit out. The animal proteins and dried reagents absorbed into the nitrocellulose membrane and the fiber conjugate pad are very unlikely to be ingested or be hazardous by ingestion. However, a physician should be consulted should ingestion occur.



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4.2. Most important symptoms and effects, both acute and delayed

None known.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

No direct contact with water.

5.2. Special hazards arising from the substance or mixture

This material will not significantly contribute to the intensity of a fire. When involved in a fire, this material can be decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide, sulfuric dioxide)

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8 for recommendations on the use of personal protective equipment. Avoid contact with skin and eyes.

6.2. Environmental precautions

Avoid the ground to be contaminated, natural water courses and wastewater drainage.

6.3. Methods and material for containment and cleaning up

Small spills: wipe up with absorbent material (e.g. cloth, fleece).

Then rinse the spillage site with plenty of water. Dispose of in accordance with section 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

See section 8 for recommendations on the use of personal protective equipment. Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Use according to instruction.

Keep away from heat, sources of ignition and direct sunlight.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Keep product at 2-30°C. Do not freeze or expose to temperature higher than 30°C. Keep away from children. Store frost-free.

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VQ81706 – MALARIA MBPan**7.3. Specific end use(s)**

This product should only be used for applications described in section 1.2.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

CAS#	Chemical Name	Limits 15 min.	Limits 8 h	Ref./comments
26628-22-8	Sodium Azide	0.3 mg/m ³	0.1 mg/m ³	EH40/Sk

Sk: Can be absorbed through the skin.

DNEL/PNEC: --

8.2. Exposure controls

Suitable engineering controls:

Concentrations in the air should be kept as low as possible. Use, for example, an exhaust system if the normal air flow in the workroom is not sufficient.

General information / hygiene measures:

Smoking, consumption of food or liquid, and storage of tobacco, food or liquid, are not allowed in the workroom. Always wash hands, forearms and face. Make sure that eyewash station are available.

Personal protective measures:

only CE-marked personal protection equipment should be used.

HAND PROTECTION

When handling the pure product use chemical resistant protective gloves (EN 374). Option: Nitrile rubber ≥60 min or similar. Thickness: ≥0,25 mm.

SKIN PROTECTION

Lab coat as indicated by general lab practice guidelines.

EYE PROTECTION

When handling the pure product use safety glasses (EN166).

RESPIRATORY PROTECTION

Not needed for normal use.

ENVIRONMENTAL EXPOSURE CONTROLS

No special precautions are necessary.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Sample diluent

Properties	Value	Information
Appearance	Liquid	
Colour	colourless	
Odour	weak	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	



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pH	Not determined
Kinematic viscosity	Not determined
Solubility	Liquid is soluble in water
Partition coefficient: n-octanol/water	Not determined
Vapour pressure	Not determined
Density and/or relative density	Not determined
Relative vapour density	Not determined
Particle characteristics	Not determined

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reaction known under conditions of normal use and storage.

10.2. Chemical stability

Stable under normal storage conditions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Direct sunlight. Keep away from heat, hot surfaces, sparks, open flames and other sources of ignition. No smoking.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizing agent.

10.6. Hazardous decomposition products

None at recommended storage conditions and use.

SECTION 11: Toxicological information

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

- (a) acute toxicity: not classified.
- (b) skin corrosion/dermal irritation: not classified.
- (c) severe ocular damage/eye irritation: not classified.
- (d) respiratory or skin sensitization: not classified.
- (e) germ cell mutagenicity: not classified.
- (f) carcinogenicity: not classified.
- (g) reproductive toxicity: not classified.
- (h) specific target organ toxicity (STOT) single exposure: not classified.
- (i) specific target organ toxicity (STOT) repeated exposure: not classified.
- (j) aspiration hazard: not classified.



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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Not classified.

No adverse effects on the environment are expected from the components of this kit. There is no aquatic toxicity data for this kit at this time.

12.2. Persistence and degradability

No data available for the components of this kit.

12.3. Bioaccumulative potential

No data available for the components of this kit.

12.4. Mobility in soil

No data available for the components of this kit.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

None known

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Avoid discharge to lakes, streams, sewers, etc. Not classified as hazardous waste. Dispose in a safe manner in accordance with local/national regulations. The coding of a waste stream is based on the application of the product by the consumer.

Contaminated packing

Properly cleaned container is disposed of according to packaging material, otherwise for incineration.

SECTION 14: Transport information

14.1. UN number or ID number

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name

None



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14.3. Transport hazard class(es)

None

14.4. Packing group

None

14.5. Environmental hazards

None

14.6. Special precautions for user

No data available

14.7. Maritime transport in bulk according to IMO instruments

There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.

Substances on Candidate List (art.59 REACH).

Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3

H301 Toxic if swallowed.

H310+H330 Fatal in contact with skin or if inhaled.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

No hazard to report. Classification procedure: calculation method.

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EC) 758/2013 of the European Parliament
 4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
 5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
 6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 9. Regulation (EU) 517/2013 of Council
 10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
 12. Regulation (EU) 2015/491 of the European Parliament
 13. Regulation (EU) No. 1297/2014 of the Commission
 14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
 15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.



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- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones..