



SAFETY DATA SHEET

EC Regulation No. 1907/2006 (REACH) modified with 2015/830/UE

Doc. N° VT82001P SSE rev.3
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1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product number: **VT82001P**
Product name: **HEPY STOOL CARD PLUS**

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

Identified uses **Immuno-chromatographic rapid test on membrane for the detection of Helicobacter pylori antigen in human stool specimen, including controls**

1.3 Details of the supplier of the safety data sheet

Company **Mascia Brunelli S.p.A.**
Viale Monza 272, 20128 Milano, Italy.
Tel.: 0039 02 25209.1
Fax: 0039 02 2576428
E-mail: mktg@masciabrunelli.it

1.4 Emergency telephone number

Emergency Phone **0039 02 66101029 (Centro Antiveleni Niguarda Ca' Granda – Milano)**

2 – HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008

2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards – none

3 – COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Individually sealed pouch: One strip packed in a plastic cassette; 0,5 g silica gel dessicant; one plastic dropper
Sample Diluent: saline solution with surfactants and < 0.1% sodium azide as preservative
Positive Control: solution containing non infectious components and sodium azide <0.1% as preservative

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 sodium azide <0.1%. The identity of each biological substance is confidential

4- FIRST AID MEASURES

4.1 Description of first aid measures

If inhaled

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

If swallowed

Ingestion of small amounts of the Sample Diluent or Positive control should not be toxic, however, a physician should be immediately. 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.
- In case of eye contact**
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 or Positive control, immediately flush eyes with plenty of water.
- In case of skin contact**
The Sample Diluent and the positive control are not likely to be hazardous by skin contact. However in case of contact, immediately clean skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. 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.
- 4.2 Most important symptoms and effects, both acute and delayed**
no data available
- 4.3 Indication of any immediate medical attention and special treatment needed**
no data available

5 - FIRE-FIGHTING MEASURES

- 5.1 Extinguishing media** For small fires, use water or CO₂.
- 5.2 Special hazards arising from the substance or mixture**
thermal decomposition can lead to release of irritating gases and vapors.
- 5.3 Advice for firefighters**
This material will not significantly contribute to the intensity of a fire. Use extinguishing material suitable to the surrounding fire. Utilize proper personal protective equipment when responding to any fire. Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel.

6- ACCIDENTAL RELEASE MEASURES

- 6.1 Personal precautions, protective equipment and emergency procedures**
Use personal protective equipment, lab coat and gloves
- 6.2 Environmental precautions**
Given the way dispensation there is no possibility of accidental spillage in sufficient quantity to be dangerous. Avoid release to the environment
- 6.3 Methods and material for containment and cleaning up**
Use adsorbent paper towel or cloth to adsorb the spill solution and dispose or clean the contaminated surface in accordance with local procedures or appropriate standards.
- 6.4 Reference to other sections**
For disposal see section 13.

7 – HANDLING AND STORAGE

- 7.1 Precautions for safe handling** Don't eat, drink, smoke in laboratory area. Use the product according to the product insert.
- 7.2 Conditions for safe storage, including any incompatibilities**
Keep product at 2-30°C in a dry place. Do not freeze or expose to temperature higher than 30°C. Keep away from children.
- 7.3 Specific end use(s)**
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8- EXPOSURE CONTROLS - PERSONAL PROTECTION

- 8.1 Control parameters** Any specific protection and prevention measures should not be taken during use of the product.
- Components with workplace control parameters**
No information available
- 8.2 Exposure controls** All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Personal protective equipment**
- Eye/face protection** Use safety glasses.

**Skin protection**
Body Protection

Handle with gloves. Use with a lab coat.
The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required.

9 – PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

	Card	Diluent/Negative control	Positive Control
a) Appearance Form:	white solid with yellow lines	transparent slightly yellowish, liquid	transparent liquid colorless
b) Odour	odorless		odorless
c) Odour Threshold	no data available		no data available
d) pH	no data available		no data available
e) Melting point/freezing point	no data available		no data available
f) Initial boiling point and boiling range	no data available		no data available
g) Flash point	no data available		no data available
h) Evaporation rate	no data available		no data available
i) Vapour pressure	no data available		no data available
j) Vapour density	no data available		no data available
k) Relative density	no data available		no data available
l) Water solubility	no data available		no data available
m) Viscosity	no data available		no data available
n) Explosive properties	no data available		no data available
o) Oxidizing properties	no data available		no data available

9.2 Other safety information

no data available

10 – STABILITY AND REACTIVITY

10.1 Reactivity	No known hazardous reactivity
10.2 Chemical stability	Stable under recommended storage conditions.
10.3 Possibility of hazardous reactions	no data available
10.4 Conditions to avoid	Direct contact with a flame. Temperatures outside the range of 2-30 ° C. Avoid storing in places with high humidity.
10.5 Incompatible materials	The stool sample should be treated only with buffer that is provided with the product before testing.
10.6 Hazardous decomposition products	no known hazardous decomposition products

11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
Acute toxicity	Product does not present an acute toxicity hazard based on known or supplied information
Skin corrosion/irritation	No data available.
Serious eye damage/irritation	No data available.
Respiratory or skin sensitisation	No data available.
Germ cell mutagenicity	No data available.
Carcinogenicity	A4-Not classifiable as a Human Carcinogen.
Reproductive toxicity	No data available.
Summary of evaluation of the CMR properties	No data available.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	No data available

12 – ECOLOGICAL INFORMATION

12.1 Toxicity	no data available
12.2 Persistence and degradability	no data available
12.3 Bio accumulative potential	no data available
12.4 Mobility in soil	no data available
12.5 Results of PBT and vPvB assessment	no data available
12.6 Other adverse effects	no data available



13 – DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Contaminated packaging

Do not remove labels from containers for disposal or recycling. Observe all the attention and precautions listed for the product.

14 – TRANSPORT INFORMATION

The product is considered non dangerous for transportation

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

no data available

15 – REGULATORY INFORMATION

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

This product does not require special labelling, in accordance with the appropriate EC directives. These products are used for in vitro diagnosis, so they must meet the criteria described in Directive 98/79/CE

15.2 Chemical Safety Assessment

no data available

16 – OTHER INFORMATION

The information in this MSDS was obtained from current and reliable sources. Anyone using this information is solely responsible for the accuracy and applicability of this information to a particular use or situation.

No one is relieved from liability for the use of the information contained in this safety data sheet.

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