



SAFETY DATA SHEET

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

Doc. N° VC1030 SSE rev.2

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1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product number:

VC1030

Product name:

ENTAMEBA Ag CARD

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 antigen of *Entamoeba spp* in faecal specimen, including controls

1.3 Details of the supplier of the safety data sheet

Company

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Viale Monza 272, 20128 Milano, Italy.

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1.4 Emergency telephone number

Emergency Phone
(Milano)

0039 02 66101029 (Centro Antiveleni Niguarda Ca' Granda –

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

Sample Diluent / Negative Control:

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.

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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

Handle with gloves. Use with a lab coat.

**Body Protection**

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.

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