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SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006

Doc. N° VC1021 SSE rev.4 Revision Date: 21-05-2015 Date of issue: 28-12-2011

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

1.1	Product identifiers	
Pro	duct number:	

Product name:

VC1021 CRYPTO+GIARDIA DIPSTICK

1.2 Relevant identified uses of the substance or mixture and uses advised against Identified uses Immunochromatographic rapid test on strip for the qualitative detection of *Cryptosporidium* and *Giardia Iamblia* antigens in faeces specimens

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: <u>mktg@masciabrunelli.it</u>

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 This substance is not classified as dangerous according to EC Directives 67/548/EEC or 199/45/EC

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				
Strip:	strips composed of several layers: an absorbent material pre-dryed with a coloured latex-antibodies conjugate against the product antigens, a nitro-cellulose membrane with coated antibodies against the product antigens and a cellulose absorbent. Contains sodium azide as preservative;			
Sample Diluent:	saline solution with surfactants and <0.1% sodium azide as preservative			

4- FIRST AID MEASURES

4.1 Description of first aid measures If inhaled

If swallowed

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. Ingestion of small amounts of the Sample Diluent 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

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L.						
In case of eye contact	by ingestion. However, a physician should be consulted should ingestion occur. 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.					
In case of skin contact	The Sample Diluent, immediately hush eyes with plenty of water. The Sample Diluent is 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, bot						
	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 CO ₂ .					
5.2 Special hazards arising from the substance or mixture						
	thermal decomposition can lead to release of irritating gases and					
5.3 Advice for firefighters	vapors. 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	nt and emergency procedures					
6.2 Environmental precautions	Use personal protective equipment, lab coat and gloves 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						
6.4 Reference to other sections	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. 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					
7.2 Conditions for safe starses including and	to the product insert.					
7.2 Conditions for safe storage, including any7.3 Specific end use(s)	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. 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					
8.2 Exposure controls	No information available All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.				
Personal protective equipment Eye/face protection Skin protection	Use safety glasses. Handle with gloves. Use with a lab coat.				

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Body Protection

Respiratory 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 is not required.

9 – PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical	nroperties		
3.1 mormation on basic physical and chemical	Strip	Diluent	
a) Appearance Form:	white solid with yellow lines	transparent slightly	
, ,,,		yellowish, liquid	
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	
I) 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	
o) Oxidizing properties		no dala avaliable	
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 h		
10.5 Incompatible materials	The sample should be treated on	ly 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	B I I I I I I I I I I		
Acute toxicity		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			
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

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Product

Contaminated packaging

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

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 transportation14.1 UN numberADR/RID: - IMDG: - IATA: -14.2 UN proper shipping nameADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods14.3 Transport hazard class(es)ADR/RID: - IMDG: - IATA: -14.4 Packaging groupADR/RID: - IMDG: - IATA: -14.5 Environmental hazardsADR/RID: no IMDG Marine pollutant: no IATA: no
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 no data available

15.2 Chemical Safety Assessment

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.

Mascia Brunelli S.p.A. does not in any way warrant or imply the applicability, viability or use of this information to any person or for use in any situation.

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