

SAFETY DATA SHEET

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

Doc. N° VT81520 SSE rev.5 Revision Date: 03-05-2018 Date of issue: 20-12-2013

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

1.1 Product identifiers

Product number: VT81520

Product name: Hb FECALE

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

Identified uses Immunoch

Immunochromatographic rapid test for the detection of human blood haemoglobin in human faecal samples,

including Positive control

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

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

Diluent / extraction buffer: 0.1 M Tris-HCl buffered saline, with Bovine Albumin (BSA) and 0.05%

sodium azide

Positive control: H. haemoglobin

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. Ingestion of small amounts of the Sample Diluent or Positive control

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



Pag: 2/4

ingested or be hazardous by ingestion. However, a physician should

be consulted should ingestion occur.

The test device is very unlikely to be contacted by eye, however, In case of eye contact

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

no data available. 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

Use safety glasses.

handled in the same manner as an infectious agent.

Personal protective equipment

Eye/face protection

Skin protection Handle with gloves. Use with a lab coat.

Mascia Brunelli S.p.A., Viale Monza 272, 20128 Milan, Italy. Tel. n°++39 02 25209.1, Fax n° ++39 02 2576428 E-mail: mktg@masciabrunelli.it; Web Site: www.masciabrunelli.it

scia Brunelli S.p.A. Pag: 3/4

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	l properties		
	Strip	Diluent	and Positive Control
a) Appearance Form:	white solid		liquid transparent 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
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
of Oxidizing properties	no data available		no data avallable
9.2 Other safety information	no data available		
10 – STABILITY AND REACTIVITY			
10.1 Reactivity	no data available		
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	a flame. T	emperatures outside the range of 2-30°
	C. Avoid storing in p		
			ect sunlight for prolonged periods. Only
	to be used for samp		
10.5 Incompatible materials	no data available.		
10.6 Hazardous decomposition products	nitrocellulose membrane can dissolve in amines esters, ketones and		
			with strong acids or alkalies
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	ו	
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 Wasto troatment methods			

13.1 Waste treatment methods

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

local environmental control regulations.

Contaminated packagingDo 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: -



cia Brunelli S.p.A. Pag: 4/4

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.

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.

First issue: 20-12-2013 Date of revision: 03-05-2018

Revision N°: rev 5