

Mascia Brunelli S.p.A.

VT81510
Hb FECALE

Scheda di Dati di Sicurezza / Safety Data Sheet

Conforme all'Allegato II del REACH - Regolamento (UE) 2020/878
According to Annex II to REACH - Regulation 2020/878

Codice / Code:	VT81510
Nome prodotto / Product name:	Hb FECALE
Descrizione d'uso / Intended use:	Test immunocromatografico rapido qualitativo per la determinazione dell'Emoglobina umana in campioni fecali / Immunochromatographic rapid test for the detection of human blood haemoglobin in human faecal samples
Fornitore / Supplier:	Mascia Brunelli S.p.A. Viale Monza 272, 20128 Milano, Italia. Tel.: 0039 02 252091 E-mail: mktg@masciabrunelli.it
Componenti del kit / Kit components:	1. FOB CARD 2. FOB Collection Tube



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SAFETY DATA SHEET

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

1.1 Product identifiers

Code: **VT81510**
Product name: **Hb FECALE**

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

Identified use: Immunochromatographic rapid test for the detection of human blood haemoglobin in human faecal samples

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

The product is not classified as 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

Hazard labelling pursuant to EC Regulation 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.

No information on other hazards.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant



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3.2 Mixtures

Individually sealed pouch: One strip packed in a plastic cassette; 0,5 g silica gel dessicant

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

The components are not hazardous or are below required disclosure limits.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: unlikely. Supply fresh air; consult doctor in case of complaint.

Direct skin contact: wash thoroughly with soap and water.

Direct eye contact: The test device is very unlikely to be contacted by eye, however, contact physician should a contact occur. Rinse cautiously with water for several minutes.

Ingestion: unlikely. If this happens, rinse the mouth with water. Seek medical attention in case of complaint.

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

Slightly irritant to skin.

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

Information not available

SECTION 5: Fire fighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

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

5.2. Special hazards arising from the substance or mixture

Information not available

5.3. Advice for firefighters

Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

6.2. Environmental precautions

Do not allow the product to enter sewers/surface or ground water.

6.3. Methods and material for containment and cleaning up

Dispose of contaminated material as waste according to Section 13. Rinse off area with water.



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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

Avoid contact with skin and eyes. Keep out of reach of children.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Store in the original container at 4 to 30°C.

7.3. Specific end use(s)

Professional uses:
Use as per instructions for use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION

Disposable gloves, latex/natural rubber/nitrile rubber.

SKIN PROTECTION

Wear normal work clothing.

EYE PROTECTION

None required for normal use.

RESPIRATORY PROTECTION

None required for normal use.

THERMAL HAZARDS

No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS

Use according to good working practices, avoiding spillage into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Solid	
Colour	White	
Odour	No odour	
Melting point / freezing point	Not applicable	

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Initial boiling point	Not applicable
Flammability	Not applicable
Lower explosive limit	Not explosive
Upper explosive limit	Not applicable
Flash point	Not applicable
Auto-ignition temperature	Not determined
pH	Not determined
Kinematic viscosity	Not determined
Solubility	Insoluble
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

Information not available

9.2.2. Other safety characteristics

Information not available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No reactivity hazards.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

Direct contact with a flame. Temperatures outside the range of 4-30° C. Avoid storing in places with high humidity.

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

(a) acute toxicity: based on available data, the classification criteria are not met

(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met



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- (c) severe ocular damage/eye irritation: based on available data the classification criteria are not met
- (d) respiratory or skin sensitization: based on available data the classification criteria are not met
- (e) germ cell mutagenicity: based on available data the classification criteria are not met
- (f) carcinogenicity: based on available data the classification criteria are not met
- (g) reproductive toxicity: based on available data the classification criteria are not met
- (h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
- (i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
- (j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances with endocrine-disrupting properties.

11.2.2. Other information

No information on other hazards.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment. The product does not contain significant quantities of ingredients that are environmentally toxic.

12.2. Persistence and degradability

The product is non-biodegradable.

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

The product is predicted to have immobility in soil.

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

Information not available

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number



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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

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

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

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



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- 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.
- 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.



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SAFETY DATA SHEET

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

1.1 Product identifiers

Code: **VT81510**
Product name: **Hb FECALE_FOB Collection Tube**

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

Identified use: Buffer solution for dilute the faecal sample

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

The product is not classified as 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

Hazard labelling pursuant to EC Regulation 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.

No information on other hazards.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant



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3.2 Mixtures

Fob Collection Tube, sample diluent: Buffer solution for sample dilution, in plastic bottles

The components are not hazardous or are below required disclosure limits.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: unlikely. Supply fresh air; consult doctor in case of complaint.

Direct skin contact: wash thoroughly with soap and water. Remove contaminated clothing and wash clothing before reuse.

Direct eye contact: Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.

Ingestion: Rinse the mouth with water. Seek medical attention in case of complaint.

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

Slightly irritant to skin.

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

Information not available

SECTION 5: Fire fighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

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

5.2. Special hazards arising from the substance or mixture

Information not available

5.3. Advice for firefighters

Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Refer to Section 8 for protective measures when handling the spillage.

6.2. Environmental precautions

Do not allow the product to enter sewers/surface or ground water.

6.3. Methods and material for containment and cleaning up

Dispose of contaminated material as waste according to Section 13. Rinse off area with water.

6.4. Reference to other sections

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



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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes. Keep out of reach of children.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Store in the original container at 4 to 30°C.

7.3. Specific end use(s)

Professional uses:
Use as per instructions for use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
Disposable gloves, latex/natural rubber/nitrile rubber.

SKIN PROTECTION
Wear normal work clothing.

EYE PROTECTION
None required for normal use.

RESPIRATORY PROTECTION
None required for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good working practices, avoiding spillage into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	
Colour	Colourless	
Odour	Odourless	
Melting point / freezing point	Not applicable	
Initial boiling point	Not applicable	
Flammability	Not applicable	
Lower explosive limit	Not explosive	

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Upper explosive limit	Not applicable
Flash point	Not applicable
Auto-ignition temperature	Not determined
pH	Not determined
Kinematic viscosity	Not determined
Solubility	Soluble
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

Information not available

9.2.2. Other safety characteristics

Information not available

SECTION 10: Stability and reactivity**10.1. Reactivity**

No reactivity hazards.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

Direct contact with a flame. Temperatures outside the range of 4-30° C.

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

- (a) acute toxicity: based on available data, the classification criteria are not met
- (b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met
- (c) severe ocular damage/eye irritation: based on available data the classification criteria are not met
- (d) respiratory or skin sensitization: based on available data the classification criteria are not met
- (e) germ cell mutagenicity: based on available data the classification criteria are not met
- (f) carcinogenicity: based on available data the classification criteria are not met



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- (g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances with endocrine-disrupting properties.

11.2.2. Other information

No information on other hazards.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment. The product does not contain significant quantities of ingredients that are environmentally toxic.

12.2. Persistence and degradability

The product is non-biodegradable.

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

The product is predicted to have immobility in soil.

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

Information not available

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

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.



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14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

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

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.
- Handling Chemical Safety



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- 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:

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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.