



**Mascia Brunelli S.p.A.**

**VP80417 –  $\beta$ -HCG MONOSTEP TEST**

Revision nr. 8

Dated 19/04/2024

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Replaced revision: 7 (Printed on: 02/05/2018)

# SAFETY DATA SHEET

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

### 1.1 Product identifiers

Code: **VP80417**  
Product name:  **$\beta$ -HCG MONOSTEP TEST**

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

Identified use: **Immunochemical test for the determination of Chorionic Gonadotropin in urine**  
Sectors of use: **professional use**  
Use advised against: **do not use for purposes other than those listed**

### 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](mailto: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:

Skin Irrit. 1

H317 May cause an allergic skin reaction.

### 2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: none

Signal words: none

Hazard statements: none

**Contains:** Mixture: 5-Chloro-2-methyl-4-isothiazolin-3-one e 2-Methyl-2H-isothiazol-3-one (3:1) – ProClin 300

### 2.3 Other hazards

At this concentration (0.02%) of Proclin 300, this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested. ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reaction in certain sensitive individuals [H317].

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.



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The mixture does not contain substances included in the list established in accordance with Article 59(1) of REACH to have endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set forth in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

### SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Irrilevant.

#### 3.2 Mixtures

Identification	x = Conc. %	Classification 1272/2008 (CLP)	Specific concentration limits
<b>Mix 5-Chloro-2-methyl-4-isothiazolin-3-one e 2-methyl-2H-isothiazol-3-one (3:1) (Proclin 300)</b>			
CAS: 55965-84-9	x < 0,001	Acute Tox. 2, H310	Skin Corr. 1C, H314 C $\geq$ 0.6%
EC: --		Acute Tox. 3, H301	Skin Irrit. 2, H315 0.06% $\leq$ C < 0.6%
INDEX – No.: 613-167-00-5		Skin Corr. 1C, H314	Eye Dam. 1, H318 C $\geq$ 0.6%
REACH-no: --		Eye Dam. 1, H318	Eye Irrit. 2, H319 0.06% $\leq$ C < 0.6%
		Skin Sens. 1A, H317	Skin Sens. 1A, H317 C $\geq$ 0.0015%
		Acute Tox. 2, H330	M (acute) = 100
		Acute Aquatic 1, H400	M (chronic) = 100
		Chronic Aquatic 1, H410	

The full text of the hazard statements (H) can be found in section 16 of the sheet.

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

GENERAL: Due to lack of classification, no symptoms or adverse effects are expected if the product is used as intended.

EYES: Rinse eyes with plenty of water for at least 15 minutes. To ensure adequate rinsing, separate eyelids with fingers while rinsing with water. SEEK MEDICAL ATTENTION.

SKIN: Remove affected clothing and wash the entire exposed skin area with mild soap and water, followed by a warm water rinse.

INGESTION: If swallowed, wash the mouth thoroughly with water, if the person is conscious, and seek medical attention. Call a doctor or local poison control center. Treat in a symptomatic and supportive manner. If vomiting occurs, keep head lower than hips to prevent aspiration.

INHALATION: No specific first aid measures were noted. In case of malaise, seek medical attention.

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

Symptoms and effects: Not expected to present a significant hazard under the expected conditions of normal use.

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

Data no available.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT

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

UNSUITABLE EXTINGUISHING EQUIPMENT

None.

#### 5.2. Special hazards arising from the substance or mixture

No specific hazardous decomposition products noted.

#### 5.3. Advice for firefighters



1. Wear usual Firefighter Personal Protective Equipment.
2. Use dry-chemical fire extinguisher.
3. Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
4. Protection during firefighting: Do not enter fire area without proper personal protective equipment, including respiratory protection (EN137).

## **SECTION 6: Accidental release measures**

### **6.1. Personal precautions, protective equipment and emergency procedures**

For those not taking direct action:

- (a) General measures: Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) - see Section 8.
- (b) Emergency procedures : Evacuate unnecessary personnel.

For direct interveners:

Protective equipment : Equip cleanup and emergency crew with proper protection.

### **6.2. Environmental precautions**

Keep away from drains surface and ground water. Dispose as infectious material.

### **6.3. Methods and material for containment and cleaning up**

Kept in the primary package and secondary package before use.  
For cleaning up, clean up with broom

### **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**

Wear appropriate personal protective equipment - see Section 8. Used device to be handled as infectious  
Do not eat, drink or smoke in the area where specimens and kits are handled. Wash hands after use.  
Contaminated clothing and protective equipment must be removed before entering eating areas.

### **7.2. Conditions for safe storage, including any incompatibilities**

Information about storage conditions: Note the storage conditions on product packaging.  
Requirements for storage rooms and containers: Store 2-30°C . Keep away from sunlight and Keep dry.

### **7.3. Specific end use(s)**

A rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

## **SECTION 8: Exposure controls/personal protection**

### **8.1. Control parameters**

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

### **8.2. Exposure controls**

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

#### **GENERAL PROTECTIVE AND HYGIENIC MEASURES**

Adhere to good laboratory practices (GLP) Wash hands before breaks and at the end of work.

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Protective gloves in latex/natural rubber.

**SKIN PROTECTION**

Lab personal protective equipment (PPE).

**EYE PROTECTION**

Safety glasses.

**RESPIRATORY PROTECTION**

Not required.

**ENVIRONMENTAL EXPOSURE CONTROLS**

There are no special precautions and measures. See section 6 and 7!

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

<b>Properties</b>	<b>Value</b>	<b>Information</b>
Appearance	Solid	
Colour	White appearance and some content of the test strip is purple	
Odour	Odourless	
Melting point / freezing point	Not applicable	
Initial boiling point	Not applicable	
Flammability	Not applicable	
Lower explosive limit	There is no substances in the kit could lead to the danger of explosion	
Upper explosive limit	There is no substances in the kit could lead to the danger of explosion	
Flash point	Not applicable	
Auto-ignition temperature	Product is not known to be self-igniting	
pH	Not determined	
Kinematic viscosity	Not applicable	
Solubility	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Vapour pressure	Not applicable	
Density and/or relative density	Not applicable	
Relative vapour density	Not applicable	
Particle characteristics	Not applicable	

**9.2. Other information****9.2.1. Information with regard to physical hazard classes**

Irrrelevant.

**9.2.2. Other safety characteristics**

Irrrelevant.

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

The product is stable in accordance with the recommended storage conditions.

**10.2. Chemical stability**

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Stable under normal conditions.

**10.3. Possibility of hazardous reactions**

There are no known hazardous reactions under normal conditions of storage and use.

**10.4. Conditions to avoid**

No known conditions.

**10.5. Incompatible materials**

None.

**10.6. Hazardous decomposition products**

None.

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

ACUTE TOXICITY: data not available.

SKIN CORROSION/DERMAL IRRITATION: based on available data, the classification criteria are not met.

SEVERE OCULAR DAMAGE/EYE IRRITATION: based on available data, the classification criteria are not met.

RESPIRATORY OR SKIN SENSITIZATION: Contains a small volume of a very dilute, sensitizing preservative (ProClin™ 300). Though the potential for an allergic response is greatly reduced by the dilution, sensitization threshold is unknown; thus, handle accordingly.

GERM CELL MUTAGENICITY: based on available data, the classification criteria are not met.

CARCINOGENICITY: based on available data the classification criteria are not met

REPRODUCTIVE TOXICITY: based on available data, the classification criteria are not met..

SPECIFIC TARGET ORGAN TOXICITY (STOT) SINGLE EXPOSURE: based on available data the classification criteria are not met

SPECIFIC TARGET ORGAN TOXICITY (STOT) REPEATED EXPOSURE: based on available data, the classification criteria are not met.

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, the product does not contain any substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

**11.2.2. Other information**

No data available.

**SECTION 12: Ecological information****12.1. Toxicity**

No data available.

**12.2. Persistence and degradability**

No data available.

**12.3. Bioaccumulative potential**

No data available.

**12.4. Mobility in soil**

No data available.

**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**

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

**12.7. Other adverse effects**

No data available.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Product:**

Do not discharge into drains or the environment. Used device to be handled as infectious. Can be disposed or incinerated according to local regulations. Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

**Packaging:**

Disposal must be made in accordance with local waste management regulations. Contaminated packaging must be disposed of in the same manner as the product. Non-Contaminated packaging materials may be recycled. Contact your local service providers for further information.

**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.

**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**

Not applicable

**14.7. Maritime transport in bulk according to IMO instruments**

Irrilevant



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## **SECTION 15: Regulatory information**

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

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC  
REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

Update according to COMMISSION REGULATION(EU) 2020/878 of 18 June 2020 and Guidance on the compilation of safety data sheets Version 4.0.

### **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**

Description of the hazard statements exposed to point 3

H301 = Toxic if swallowed.  
H310 = Fatal in contact with skin.  
H314 = Causes severe skin burns and eye damage.  
H317 = May cause an allergic skin reaction.  
H318 = Causes serious eye damage.  
H330 = Fatal if inhaled .  
H400 = Very toxic to aquatic life.  
H410 = Very toxic to aquatic life with long lasting effects.

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
  - 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.