



#### IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE **COMPANY/UNDERTAKING**

Product identifier 1.1

Trade Name: hCG Pregnancy Rapid Test

FHC-101/102/103/201/202/111/211//U102/U201/U202/U111/U211 Catalog Number:

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

Rapid Test kit for In vitro Diagnostic

Details of the suppleier of the safety data sheet

ACRO BIOTECH, Inc. Manufacturer:

Address: 9500, 7th str., Rancho Cucamonga

CA 91730, USA

Phone number: +1-909-466-6857 +1-909-466-6892 Fax number: E-Mail Contact Person: info@acrobiotech.com

1.4 **Emergency Telefone Number** 

Contact the regional poison Control Center

#### HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008 appendix VII: Not applicable

**Chemical Ingredient Chemical Data / Information** 

Classification according to regulation 67/548/EEC or regulation 1999/45/EC: Not applicable

#### 2.2 Label elements

#### Labelling according to regulation (EC) No. 1272/2008

The product does not need to be labelled in accordance with EC directives or respective national laws.

Hazard picograms and Signal word:

3.1

Hazardous components for labeling: No

Hazard statements: No Precautionary statements: No

**Substances** This product is a mixture

#### 2.3 Other hazards

At this concentration (0.02%), this biocidal preservative is irritating to eyes and skin, and may be detrimental if enough is ingested ( quantities above those found in the kit). ProClin 300 is a skin sensitizer; prolonged or repeated exposure may cause allergic reactio n in certain sensitive individuals [H317].

#### **COMPOSITION / INFORMATION ON INGREDIENTS**

#### 3.2 **Mixtures Hazardous** CAS No. **EINECS No. REACH** Classification: W/W % Registration No. Codes/ ingredients Category Hazard statement Mixture of 5-Chloro-2-55965-84-9 N/A Not available Acute Tox. 3: H301-H311-0,001 % methyl-4-isothiazolin-3one and 2-Methyl-2H -Skin Corr. 1B: H314 Skin Sens. 1: H317 isothiazol-3-one (3:1)

Aquatic Acute 1; H400 Aquatic Chronic 1; H410

Lowest generic cut-off value according to Table 1.1 Annex  $I: \ge 0.1$ 

Lowest specific concentration limits according to Table 3.1 Annex VI:

Skin Corr. 1B; H314 C ≥ 0.6 %

Skin Irrit. 2; H315:  $0.06 \% \le C < 0.6 \%$ Eye Irrit. 2; H319:  $0.06 \% \le C < 0.6 \%$ Skin Sens. 1; H317:  $C \ge 0.015 \%$ 

#### FIRST-AID MEASURES

4.1 Description of first aid measures		
After inhalation	Remove person from exposure area to fresh air. If breathing becomes difficult, immediately call for	
	emergency medical assistance. Treat symptomatically and supportively. Generally, this aqueous product is	
	not a significant inhalation hazard in the kit volumes and concentrations present.	

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After skin contact Remove contaminated clothing. Flush skin with copious water and wash affected area with so	
	If blood-to-blood contact occurs or if more severe symptoms develop, consult a physician.
After eye contact	Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids
	with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.
After Ingestion	If ingested, wash out mouth thoroughly with water, provided the person is conscious, and OBTAIN
	MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and
	supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.
4.2 Most impor	tant symptoms and effects, both acute and delayed
Not applicable.	
4.3 Indication of	f any immediate medical attention and special treatment needed
No data available.	

5 FIRE-FIGHTING MEASURES		
5.1 Extinguishing media		
Suitable extinguishing media:	The common fire extinguish media can be used	
Unsuitable extinguishing media:	Not investigate	
5.2 Special hazards arising from the substance or mixture		
Not find yet		
5.3 Advice for fire-fighters		
dry-chemical fire extinguisher		

## 6 ACCIDENTAL RELEASE MEASURES

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

Avoid direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab personal protective equipment (PPE) including gloves, lab coat and eye/face protection.

#### **6.2** Environmental precautions

Avoid release to the environment.

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

Clean up with broom.

## 6.4 Reference to other sections

Collect material and dispose of waste according to section 13.

## 7 HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

**General hygiene measures:** 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 remove 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 in a cool dry place.

## 7.3 Specific end uses

Rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in human plasma, serum or urine.

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	
8.2.1 Appropriate engineering controls	
Handle in accordance with good industrial hygiene a	nd safety practice. Wash hands before breaks and at the end of workday.
8.2.2 Personal protective equipment	
General protective and hygienic measures:	Adhere to good laboratory practices (GLP)
	Wash hands before breaks and at the end of work.
Respiratory protection	Not required
Protective gloves	Disposable gloves
Material of gloves	Latex/natural rubber
Penetration time of glove material	Gloves resistance is not critical when the product is handled according to the
	instruction for use.
Eye Protection	Safety glasses

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Body protection	Lab coat
8.2.3 Environmental exposure controls	
There are no special precautions and measures. See s	ection 6 and 7!

9 PHYSICAL AND CHEMICAL PROPERTIES		
9.1 Information	9.1 Information on basic physical and chemical properties	
Physical State:	Solid	
Colour:	White appearance and some content of the test strip is purple	
Odour:	tasteness	
Odour threshold:	Not established	
Flash point:	Not established	
Self-igniting:	Product is not known to be self-igniting	
Danger of explosion:	There is no substances in the kit could lead to the danger of explosion	
Melting point:	Not established	
Boiling point:	Not established	
Vapour pressure:	Not established	
Density (20°C):	Not established	
pH-value at 20°C:	Not established	
Solubility in water:	The product almost could not solute in the water	
9.2 Other safety information:		
No		

	10 STABILITY AND REACTIVITY
10.1	Reactivity
The prod	luct is stable in accordance with the recommended storage conditions.
10.2	Chemical stability
All the cl	hemicals in the test kits are stable.
10.3	Possibility of hazardous reactions
Almost i	mpossible
10.4	Conditions to avoid
High hur	midity and the temperature out of $2-30^{\circ}\mathrm{C}$
10.5	Incompatible materials
No	
10.6	Hazardous decomposition products
No	

11 TOXICOLOGICAL INFORMATION			
11.1 Information on to	11.1 Information on toxicological effects (Mixture)		
Acute toxicity:	Quantitative date on the toxic effects of this product is not available.		
Irritation:	Irritating to skin and severely irritating or corrosive to eyes and, with greater exposures, can cause eye damage, including permanent impairment of vision or blindness.		
Corrosivity:	Corrosive to eyes; with greater exposures may cause eye injury. Harmful if swallowed.		
Sensitisation:	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.		
Repeated dose toxicity:	Not yet investigate		
Carcinogenicity:	Not yet investigate		
Mutagenicity:	Not yet investigate		
Toxicity for reproduction:	No reproductive toxic effect known.		

# 12 ECOLOGICAL INFORMATION

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12.1	Toxicity
No data	available
12.2	Persistence and degradability
	available
12.3	Bioaccumulative potential
No data	available
12.4	Mobility in soil
No data	available
12.5	Results of PBT and vPvB assessment
PBT/vPv	vB assessment not available as chemical safety assessment not required/not conducted
12.6	Other adverse effects
No data	available

13 DISPOSAL CONSIDERATIONS		
13.1 Waste treatment methods		
Product:	Chemical residues and remains should be routinely handled as spezial 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.	
European waste catalogue:	18 01 03 wastes whose collection and disposable is subject to spezial requirements in order to prevent infection.	
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 informations.	

14 TRANSPORT INFORMATION
14.1 UN proper shipping name
ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods
14.2 Transport hazard class
ADR/RID: - IMDG: - IATA: -
14.3 Packing group
ADR/RID: - IMDG: - IATA: -
14.4 Environmental hazards
ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR:  yes / \no  Marine Pollutant : yes / \no
14.5 Special precautions for user
See sections 6-8
14.6 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Delivery will only be taken in suitable and regulatory approved packaging

# 15. REGULATORY INFORMATION 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU regulations: This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006. 15.2 Chemical Safety Assessment The mixture was not subjected to security assessment

## 16 OTHER INFORMATION

#### **General information**

The potential for adverse health effects is unknown for the highly diluted, small volume of ProClin 300 in this kit, but is unlikely if handled appropriately with the requisite Good Laboratory Practices and Universal Precautions. This material and its container must be disposed of in a safe way and in accordance with local, regional, national and international regulations [P501]. The information and recommendations presented in this MSDS are based on sources believed to be accurate. It is the user's

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responsibility to determine the suitability of the information for their particular purposes.