

Section 1 – Product and Company Information

Product Name: *OnSite* HBsAg Rapid Test

Product Description: A lateral flow chromatographic immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg) in human serum, plasma or whole blood. It is intended to be used by healthcare professionals as an aid in the diagnosis of infection with hepatitis B virus (HBV). These tests are for *in vitro* use only.

Product Catalog: R0042C

Company: CTK Biotech, Inc
Street Address: 13855 Stowe Dr
City, State, Zip, Country: Poway, CA 92064, USA
Technical Phone: 858-457-8698
Fax: 858-535-1739
Website: www.ctkbiotech.com

Emergency Phone: 858-344-2199

Section 2 – Hazards Identification

2.1 Classification of Substance:

Substance Name	Amount	CAS#	EC Number	R-phrases	S-phrases
Proclin-300	0.05%	26172-55-4	220-239-6	R36/38 R43	S 24-35-37

According to European Directive 91/155/EEC and regulations (EC) 1272/2008 (CLP)
 Proclin-300: Hazardous labeling not required when concentration <0.06%

2.2 Label Elements:

The product does not contain a hazardous ingredient in an amount that requires identification and labelling according to the concentration limit/cut-off values of EC directives. This product contains no hazardous constituents, or the concentration of all chemical constituents is below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29 CFR 1910.1200 and the European Directive 91/155/EEC, 93/112/EC and (EC) 1272/2008 (CLP).

Bio-hazards: All the biological substances are derived from *in vitro* culture system or animal materials which are free of known-pathogens for human. Thus, no bio-hazardous can be claimed in the product.

Section 3- Composition/Information on Ingredients

	Name	Concentration	CAS No.
2. Diluent Buffer (pH 7.2-7.4)	Tris	25mM	77-86-1
	Sodium Chloride, NaCl	0.9%	7440-23-5
	Casein,	0.5%	9000-71-9
	Proclin-300	0.05%	26172-55-4
	Distilled Water	~98%	7732-18-5

Section 4 – First Aid Measures

Inhalation: Inhalation of any component in this kit is unlikely. If a component of this kit is inhaled and causes discomfort, move exposed individual to fresh air. Seek medical attention if breathing is difficult or symptoms persist.

Ingestion: Ingestion of small amounts of the Sample Diluent is toxic; a physician should be contacted 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 by ingestion. However, a physician should be consulted should ingestion occur.

Skin Contact: The Sample Diluent is hazardous by skin contact. 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.

Eye Contact: 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 for at least 15 minutes. Cold water may be used. Get medical attention.

Aggravating Condition: Repeated or prolonged exposure is not known to aggravate medical condition.

Section 5 – Firefighting measures

5.1 Extinguishing Media: For small fires, use dry chemical, carbon dioxide, or alcohol-resistant foam. No direct contact with water.

5.2 Special Fire Fighting Procedures: 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. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

5.3 Unusual Fire and Explosion Hazards: When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide, Carbon dioxide, sulfuric dioxide).

Explosion Sensitivity to Mechanical Impact: Not sensitive under normal conditions.

Explosion Sensitivity to Static Discharge: Not sensitive under normal conditions.

5.4 Additional Considerations

5.4.1 Flash Point	Non Combustible
5.4.2 Auto-ignition Temperature	Not Applicable
5.4.3 Upper / Lower Explosion Limit	Not Applicable

5.5 NFPA 704 Ratings

Sample Extraction Buffer (with 0.05% Proclin-300)



Section 6 – Accidental Release Measures

Personal Precaution: Lab coat and gloves.

Small Spill and Leak: Use absorbent paper towel or cloth to absorb the spill solution and dispose or clean the contaminated surface in accordance with U.S. Federal, State, or local procedures or appropriate standards

Large Spill and Leak: Not applicable.

Section 7 – Handling and Storage

Handling: Don't eat, drink, smoke or apply cosmetics in laboratory area. Use the product according to the product insert.

Storage: Keep container tightly closed. Keep product at 2-30°C. Do not freeze or expose to temperature higher than 30°C. Keep away from children.

Section 8 – Exposure Control/Personal Protection

8.1 Exposure Limits:

CAS#	Chemical Name	OSHA (PEL)	ACGIH (TLV) *	NIOSH
26172-55-4	Proclin-300	N/A	0.1 mg/ m ³	N/A

Biological Exposure Index (ACGIH).

Other exposure limits for potential decomposition products: None.

8.2 Occupational Exposure Controls:

Engineering Control: Eye bath. Use adequate ventilation to keep airborne concentrations low.

Hygiene Measures: Wash hands after handling compounds and before eating, smoking, using lavatory, and at the end of the day.

Personal Protective Equipment:

Respiratory Protection None needed under normal conditions of use
Skin and Body Lab coat as indicated by general lab practice guidelines.
Eyes Safety glasses or face shield are recommended to prevent eye contact.
Hand Compatible chemical resistant gloves.

Section 9 – Physical/Chemical Properties

	Boiling Point	Melting point	Special gravity	Vapor pressure	Vapor density	Evapora-Tion rate	pH	Water solubility	Appearance and odor
Procline-300	233°C	N/A	1.03	0.06mmHg	N/A	<1	4.1	Soluble	odorless

Section 10 –Stability and Reactivity

	Stability Conditions	Materials to avoid	Hazardous to avoid	Hazardous decomposition or Bio-products	Polymerization
Proclin-300 (0.1%)	Stable	Incompatible Materials	Strong oxidizers Perchloric Acid, > 25°C for prolonged periods	Hydrogen chloride, oxides of Nitrogen and sulfur	Not occur

Section 11 – Toxicological Information

No adverse effects on the health are expected from the components of the product. There is no aquatic toxicity data for this product at this time. Individual aquatic toxicity studies have been completed for the below listed chemicals.

Proclin-300

LD₅₀ oral rat, female: 3723 mg/kg
LD₅₀ oral rat, male: 3600 mg/kg
LD₅₀ skin rabbit, female:>3600 mg/kg
LD₅₀ skin rabbit, male: 3500 mg/kg

To the best of our knowledge, the chemical, physical, and toxicological properties of this chemical have not been thoroughly investigated.

Section 12 – Ecological Information

12.1 Ecotoxicity – Not Available

No adverse effects on the environment are expected from the components of this kit. There is no aquatic toxicity data for this kit at this time Individual aquatic toxicity studies have been completed for the below listed chemicals.

12.2 Mobility: Mobility data are not available for the components of this kit.

12.3 Persistence and Degradability: There is no persistence or degradation data for any component of this kit at this time.

12.4 Bioaccumulative Potential

There is limited potential for the components within this kit to accumulate in plant or animal systems.

Section 13 – Disposal Consideration

Methods of Disposal; Waste of Residues, Contaminated Packaging Waste must be disposed of in accordance with federal, state and local environmental control regulations. *This product is not considered a RCRA hazardous waste.* Accumulation in the sink may form highly explosive metal azides. Don't dispose the solid product into the sink.

Section 14 – Transport Information

14.1 U.S. Transportation

This product is regulated per 49 CFR 172.101, the U.S. department of transportation:

Proper Shipping Name: None
Non-Hazardous for Transport: This substance is considered to be non-hazardous for transport.

14.2 Canadian Transportation

The above-listed DOT basic description applies to this product under the regulations of Transport Canada.

14.3 International Air Transportation

This product is regulated per International Air Transportation Association (IATA) Dangerous Goods Regulations:

Proper Shipping Name: None

Non-Hazardous for Transport: This substance is considered to be non-hazardous for air transport.

Section 15 – Regulatory Information

15.1 U.S. Federal and State Regulations

	Proclin-300
40 CFR 355.30/355.40 - SECTION 302	Not applicable
40 CFR 302.4 – SECTION 304	Not applicable
40 CFR 372.65 – SECTION 313	Not applicable

U.S. SARA SECTION 311/312 FOR KIT: No acute health effects; no chronic health effects.
U.S. TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory.
OTHER U.S. FEDERAL REGULATIONS: Not applicable.
CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No

15.2 Label Information

ANSI 129.1 Not required for component or kit

ENVIRONMENTAL HAZARDS:

Do not discharge effluent containing this kit into streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

15.3 Canadian Regulations:

CANADIAN DSL/NDSL INVENTORY STATUS: Proclin is listed on the DSL Inventory.

CANADIAN WHMIS SYMBOLS: None Required

15.4 Hazardous Material Information System (USA)

Health	1
Fire Hazard	0
Reactivity	0
Personal Protection	B

15.5 Markings According to European Community 1999/45/EC, 2001/59/EC, 2001/60/EC, 2006/102/EC Guidelines:

This product has been classified and labeled in accordance with applicable European Community (EC) Directives

Section 16 – Other Information

Risk Phrases:

R43 May cause sensitization by skin contact.
R36/38 Irritating to eyes and skin

Safety Phrases:

S24 Avoid contact with skin.
S35 This material and its container must be disposed of in a safe way.
S37 Wear suitable protective gloves.

Notice to Reader

The contained information in this MSDS are in accordance with Annex II of Regulation no.1907/2006 (REACH) and in accordance with ANSI "Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets – Preparation" (ANSI Z400.1-2004) as recommended by US OSHA.

To the best of our knowledge, this information contained herein is accurate. However, neither the above named supplier nor may of its subsidiaries assume any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

OnSite HBsAg Rapid Test

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