

SECTION 1, IDENTIFICATION

Product Name(s): A1CNow Test Strip

Manufacturer Information:

Polymer Technology Systems, Inc.

4600 Anson Blvd.

Whitestown, IN 46075 USA

+1.317.870.5610

www.ptsdiagnostics.com

Recommended use: In vitro diagnostic testing

SECTION 2, HAZARD(S) IDENTIFICATION

Man: None determined.

Environment: None determined.

EU Classification (1999/45/EC): Not applicable.

EU Risk and Safety Phrases: None.

SECTION 3, COMPOSITION/ INFORMATION ON INGREDIENTS

The strip subcomponent contains membrane impregnated with antibody and Bovine Serum

Albumin (BSA)

Antibody (Proprietary) 0.6 – 1.0 ug of IgG Antibody

BSA 1-3 ug of BSA

SECTION 4, FIRST-AID MEASURES

Emergency First Aid Procedures:

Eye Contact: In case of eye contact immediately flush eyes with copious amounts of water for at least 15 minutes. Get medical attention if irritation persists.

Skin Contact: No special precautions required.

Inhalation: No special precautions required.

Ingestion: No special precautions required.

SECTION 5, FIRE-FIGHTING MEASURES

Extinguishing Media: Not applicable.

Special Fire Fighting Procedures: Not applicable.

Unusual Fire and Explosion Hazards: None determined.

SECTION 6, ACCIDENTAL RELEASE MEASURES

No special precautions required

SECTION 7, HANDLING AND STORAGE

A1CNow test strips are humidity sensitive (<10%RH). Test strips are packaged in a desiccated foil pouch to maintain dryness. Use gloves when handling strips.

Recommended Storage: 2-8°C at <10%RH (packaged in desiccated foil barrier pouch)

SECTION 8, EXPOSURE CONTROLS/PERSONAL PROTECTION

Ventilation: None required.

Respiratory Equipment: None required.

Protective Gloves: Avoid contact with skin. Wear gloves to prevent damage to test strips.

Eye Protection: None required.

Other Protective Equipment/Clothing: None required.

SECTION 9, PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor: White paper-like membrane with blue stripe. Odorless.

pH: N/A

Specific Gravity (H₂O=1): N/A

Boiling Point (F): N/A

Melting Point (F): N/A

Vapor Pressure: N/A

Evaporation Rate: N/A

Solubility in Water: N/A

Flash Point (Method Used): N/A

Flammable Limits:

LEL: N/A UEL: N/A

N/A = Not Applicable. N/D = Not Determined.

SECTION 10, STABILITY AND REACTIVITY

Stability: Stable

Conditions to Avoid: None determined.

Substances to Avoid: None determined.

Hazardous Decomposition Products: None determined.

Hazardous Polymerization: Will Not Occur.

SECTION 11, TOXICOLOGICAL INFORMATION

Chronic Effects of Overexposure: None currently known.

Carcinogen or Suspected Carcinogen: None of the components are listed as a carcinogen or suspected carcinogen.

Medical Conditions Aggravated by Exposure: None currently known.

Acute Toxicity:

Inhalation: None currently known.

Ingestion: None currently known.

Skin Contact: None currently known.

Eye Contact: None currently known.

Acute Toxicity Values: None currently known.

SECTION 12, ECOLOGICAL INFORMATION

No data available.

SECTION 13, DISPOSAL CONSIDERATIONS

Waste Disposal Method: Each disposal facility must determine proper disposal methods to comply with Local, State and Federal Environmental Regulations.

SECTION 14, TRANSPORT INFORMATION

Proper Shipping Name: Not regulated

Technical Name: N/A

UN Number: N/A

Hazard Class and Packaging Group: N/A

Label(s): N/A

Packing Instruction (Passenger Aircraft): N/A

Packing Instruction (Cargo Aircraft): N/A

Shipping Container Type: N/A

Sales Unit: Nominally 116 A1CNow test strips per 14" card

SECTION 15, REGULATORY INFORMATION

Canadian WHMIS Classification: Medical Devices are Exempt from WHMIS

EU Classification (1999/45/EC): Not applicable

EU Risk and Safety Phrases: None

SECTION 16, OTHER INFORMATION

Date Prepared: 12/07/2022

Revision Number: 3

Reason for Revision: Removed product REF numbers.

EU Classes and Risk Phrases for Reference (See Sections 2 and 3):

Xi – Irritant.

R36/37/38 – Irritating to eyes, respiratory system and skin.

Acute Tox. – Acute toxicity

Aquatic Acute – Acute aquatic toxicity

Eye Dam. – Serious eye damage

H302 – Harmful if swallowed.

H314 – Causes severe skin burns and eye damage.

H317 – May cause an allergic skin reaction.

H318 – Causes serious eye damage.

H331 – Toxic if inhaled.

H335 – May cause respiratory irritation.

H400 – Very toxic to aquatic life.

H410 – Very toxic to aquatic life with long lasting effects.

Skin Corr. – Skin corrosion.

Skin Sens. – Skin sensitization.

STOT SE – Specific target organ toxicity – single exposure.

The opinions expressed herein are those of qualified experts within Polymer Technology Systems, Inc. We believe that the information contained herein is current as of the date of this Safety Data Sheet. Since the use of this information and these opinions and the conditions of use of the product are not within the control of Polymer Technology Systems, Inc., it is the users' obligation to assure safe use of the product.

Polymer Technology Systems, Inc.

4600 Anson Blvd.

Whitestown, IN 46075 USA

+1.317.870.5610

www.pt diagnosti cs.com

Regulated by:
OSHA 29 CFR 1910.1200
USA/EC Directive

Page | 4 of 4