

SECTION 1, IDENTIFICATION

Product Name(s): A1CNow[®]+, A1CNow[®] Self Check

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

Restrictions on use: Use only as directed in product labeling

SECTION 2, HAZARD(S) IDENTIFICATION

Man: Sample treatment buffer contains components that may cause eye/skin/gastrointestinal/respiratory irritation. Battery, if removed and opened, may cause eye/skin burns or irritation.

Environment: None determined.

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

EU Risk and Safety Phrases: None.

SECTION 3, COMPOSITION/ INFORMATION ON INGREDIENTS

This product contains several components.

Sample Treatment Buffer

CAS-No./EINESCS-No.	Chemical Name	Amount	EU Classification (67/548/EEC):
Proprietary	Detergent (Proprietary)	2%	Xi, R36/37/38
None	No hazardous components >1%, >0.1% carcinogen	1%	Xi, R36/37/38

Battery

Battery, Maxell, GP (Gold Peak) Group, Energizer	Please contact the manufacture for the Safety Data Sheet on the Alkaline Button Cell.
--	---

This product does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III Section 313 (40 CFR 372).

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

EU Risk and Safety Phrases: None

SECTION 4, FIRST-AID MEASURES

The system (other than liquid sample treatment buffer and battery) presents no safety hazards other than a choking hazard if broken into pieces and inappropriately swallowed. The battery is not accessible unless the meter is completely destroyed. The sample treatment buffer is the only accessible component with a potential safety hazard.

The sample treatment buffer contains 2% of chemical components associated with eye, skin, inhalation or ingestion risks, but risks at this extremely diluted concentration have not been evaluated.

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: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation persists.

Inhalation: Move patient to fresh air. Get medical attention if respiratory irritation or breathing difficulties persist.

Ingestion: If the patient is conscious, rinse out mouth with water and have the patient drink a glass of water or milk to dilute the material. Contact Poison Control for additional instructions.

SECTION 5, FIRE-FIGHTING MEASURES

Sample Treatment Buffer:

The sample treatment buffer is not flammable.

Extinguishing Media: Not applicable.

Special Fire Fighting Procedures: Not applicable.

Unusual Fire and Explosion Hazards: None determined.

SECTION 6, ACCIDENTAL RELEASE MEASURES

Sample Treatment Buffer:

Steps to be taken in case material is released or spilled: Take up with absorbent material and place in a suitable container. Wipe up area with a damp paper towel and discard.

SECTION 7, HANDLING AND STORAGE**Sample Treatment Buffer:**

Store at temperatures and conditions as indicated on the product label. Avoid contact with the eyes, skin and clothing.

SECTION 8, EXPOSURE CONTROLS/PERSONAL PROTECTION**Sample Treatment Buffer:**

<i>Chemical Name</i>	<i>Exposure Limit(s)</i>
Detergent (2%)	None established

Ventilation: Use general room ventilation.

Respiratory Equipment: None required.

Protective Gloves: Avoid contact with skin.

Eye Protection: Avoid contact with eyes.

Other Protective Equipment/Clothing: Not required.

SECTION 9, PHYSICAL AND CHEMICAL PROPERTIES**Sample Treatment Buffer:**

Appearance and odor: Liquid, clear, odorless.

pH: 7.4

Specific Gravity (H₂O=1): ~1

Boiling Point (F): N/D

Melting Point (F): N/A

Vapor Pressure: N/D

Evaporation Rate: N/D

Solubility in Water: Soluble

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

Sample Treatment Buffer:

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

Sample Treatment Buffer:

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: Inhalation of mists may cause minor respiratory irritation.

Ingestion: Ingestion may cause gastrointestinal irritation, nausea and vomiting and other adverse effects.

Skin Contact: Contact may cause irritation, particularly on prolonged contact.

Eye Contact: Contact may cause irritation, particularly on prolonged contact.

Acute Toxicity Values: No data available.

SECTION 12, ECOLOGICAL INFORMATION

Sample Treatment Buffer:

Ecological effects of this mixture have not been determined.

Individual (full strength) components of the mixture are reported to be very toxic to aquatic life.

SECTION 13, DISPOSAL CONSIDERATIONS

Primary Container Type: The product container is plastic.

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

Sample Treatment Buffer Primary Container Type: The product container is plastic

Sales Unit: 1 kit

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: 5

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.

SAFETY DATA SHEET

PS-003632 Rev. 5

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.