



**Safety Data Sheet #: 80-HPYHU-FCSET**

**Revision:** 1.0      **Last Revised:** 10Jul24

**Product #** 80-HPYHU-FCSET

**Product Name:** H. Pylori Stool Antigen CLIA Re-Calibrator and Control Set

Hazards classification information for the components below are included in this SDS:

<b>Component Number</b>	<b>Component Name</b>	<b>Page</b>
900-82R1	H. Pylori Re-Calibrator	2
900-HPYNEG	H. Pylori Negative Control	2
900-HPYPOS	H. Pylori Positive Control	2



# H. Pylori CLIA Re-Calibrator and Controls Safety Data Sheet

Date of Issue: 07/10/2024

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Version: 1.0

## SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

### 1.1 Product Identifier

**Product Form:** Mixture

**Product Name and Codes:** H. Pylori Re-Calibrator (900-82R1) and Controls (900-HPYNEG and 900-HPYPOS)

### 1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Recommended Uses:** For in vitro laboratory use. For professional use only.

### 1.3 Details of the Supplier of the Safety Data Sheet

**Manufacturer's Name:** ALPCO

**Address:** 26-G Keewaydin Drive Salem, NH, US, 03079

**Information Phone Number:** 800-592-5726 Ext. 232

**Fax:** 603-898-6854

### 1.4 Emergency Telephone Number

**Emergency Phone:** 911 in the United States

## SECTION 2: Hazard Identification

### 2.1 Classification of the Substance or Mixture

#### Classification

Skin Sensitizer – Category 1

Acute Toxicity - Category 4

These classifications were evaluated according to United States Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1910.1200), the Canadian Workplace Hazardous Materials Information System (WHMIS), and to Regulation (EC) No 1272/2008.

### 2.2 Label Elements

#### Pictograms



#### Signal Word

Warning

#### Hazardous Statements - Health

H302 – Harmful if swallowed

H316 - Causes mild skin irritation

H317 - May cause an allergic skin reaction

#### Precautionary Statements - General

P101 - If medical advice is needed, have product container or label at hand.

P103 - Read label before use.

P270 - Do not eat, drink or smoke when using this product.

#### Precautionary Statements - Prevention

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.

P264 - Wash thoroughly after handling.

P272 - Contaminated work clothing should not be allowed out of the workplace.

P280 - Wear protective gloves, protective clothing, eye protection/face protection.

#### Precautionary Statements - Response

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P312 - Call a POISON CENTER/doctor if you feel unwell.

P391 - Collect spillage.

P302 + P352 - IF ON SKIN: Wash with plenty of water.

P333 + P313 - If skin irritation or a rash occurs: Get medical advice/attention.

P337 + P313 - If eye irritation persists: Get medical advice/attention.

P362 + P364 - Take off contaminated clothing. And wash it before reuse.

### Precautionary Statements - Storage

No precautionary statement available.

### Precautionary Statements - Disposal

P501 - Dispose of contents/container in accordance with local/national/international regulations.

### 2.3 Other Hazards

No additional information available.

## SECTION 3: Composition/information on Ingredients

### 3.1 Substances

Not Applicable

### 3.2 Mixtures

CAS	EC No	Chemical Name	% By Weight in Mixture	Classification according to (EC) No 1272/2008 (based on concentration present in mixture)	(EC) 1272/2008 Annex I Generic Cut-Off Limits	Specific Concentration Limit (SCL)
0009048-46-8	232-936-2	Albumins, Blood Serum	1% - 5%	Acute Toxicity Category 4	≥1%	No Data Available
0055965-84-9	932-593-5	2-Methyl-1,2-Thiazol-3(2H)-one-5-chloro-2-methyl-1,2-thiazol-3(2H)-one (1:1)	<0.04%%	Skin Sensitizer Category 1 Skin Irritant Category 2 Eye Irritant Category 2	≥0.1% ≥1% ≥1%	Skin Sens. 1: C≥0.0015% Skin Irrit. 2 0.06≤C≤0.6% Eye Irrit. 2 0.06≤C≤0.6%

## SECTION 4: First-aid Measures

### 4.1 Description of First Aid Measures

#### First Aid Measures After Inhalation

Remove source of exposure or move person to fresh air and keep comfortable for breathing.

If breathing is difficult, trained personnel should administer emergency oxygen if advised to do so by the POISON CENTER/doctor.

Call a POISON CENTER/doctor if you feel unwell.

#### First Aid Measures After Skin Contact

Rinse with lukewarm, gently flowing water for 5 minutes or until product is removed.

Take off contaminated clothing, shoes and leather goods (e.g. watchbands, belts).

If skin irritation or a rash occurs: Get medical advice/attention.

Wash contaminated clothing before re-use or discard.

#### First Aid Measures After Eye Contact

If eye irritation persists: Get medical advice/attention.

Rinse eyes cautiously with lukewarm, gently flowing water for several minutes, while holding the eyelids open.

Remove contact lenses, if present and easy to do.

Take care not to rinse contaminated water into the unaffected eye or onto the face.

#### First Aid Measure After Ingestion

Rinse mouth.

If you feel unwell/If concerned: Call a POISON CENTER/doctor.

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

Symptoms/effects after inhalation: May cause irritation of the respiratory tract.

Symptoms/effects after skin contact: May cause irritation. Repeated Exposure may cause skin dryness or cracking.

Symptoms/effects after eye contact: May cause eye irritation. Symptoms may include discomfort or pain, excess blinking and tear production, with possible redness and swelling.

Symptoms/effects after ingestion: May be harmful if swallowed. May cause gastrointestinal irritation, nausea, vomiting, and diarrhea.

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

Treat according to symptoms (decontamination, vital functions), no known specific antidote. Treatment should be supportive and based on the judgement of the physician in response to the reaction of the patient.

## SECTION 5: Fire-fighting Measures

### 5.1 Extinguishing Media

Small Fire: Dry chemical, foam, carbon dioxide, water-spray or alcohol-resistant foam. Carbon dioxide can displace oxygen. Use caution when applying carbon dioxide in confined spaces. Large Fire: Water spray, fog or alcohol-resistant foam.

#### Unsuitable Extinguishing Media

Do not use straight stream of water.

### 5.2 Special Hazards Arising from the Substance or Mixture

Products of combustion may produce, but not limited to oxides of carbon. Runoff may pollute waterways

### 5.3 Advice for Fire Fighters

Isolate immediate hazard area and keep unauthorized personnel out. Stop spill/release if it can be done safely. Move undamaged containers from immediate hazard area if it can be done safely. Cool containers with flooding quantities of water until well after fire is out. Caution should be exercised when using water or foam as frothing may occur, especially if sprayed into containers of hot, burning liquid. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

#### Special Protective Actions

Wear protective pressure self-contained breathing apparatus (SCBA) and full turnout gear.

## SECTION 6: Accidental Release Measures

### 6.1 Personal Precautions, Protective Equipment, and Emergency Procedure

Isolate hazard area and keep unauthorized personnel away. Stay uphill and/or upstream. Ventilate closed spaces before entering. Do not touch damaged containers or spilled materials unless wearing appropriate protective clothing.

#### Recommended Equipment

Wear chemical protective clothing.

#### Personal Precautions

Avoid breathing vapor or mist. Avoid contact with skin, eye, or clothing.

### 6.2 Environmental Precautions

Stop spill/release if it can be done safely. Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems and natural waterways by using sand, earth, or other appropriate barriers.

### 6.3 Methods and Materials for Containment and Cleaning up

Absorb Liquids in vermiculite, dry sand, earth, or similar inert material and deposit in sealed containers for disposal. Ventilate area after clean-up is complete.

### 6.4 Reference to Other Sections

For further information refer to section 8 "Exposure Controls/Personal Protection"

## SECTION 7: Handling and Storage

### 7.1 Precautions for Safe Handling

#### General

Wear appropriate personal protective equipment (PPE). Wash hands after use. Avoid breathing vapor or mist. Use good personal hygiene practices. Eating, drinking, and smoking in work areas is prohibited. Remove contaminated clothing and protective equipment before entering eating areas. All containers must be properly labelled. Eyewash stations and showers should be available in areas where this material is used and stored Do not get in eyes, on skin, or on clothing.

### 7.2 Conditions for Safe Storage, Including Any Incompatibilities

#### Storage Room Requirements

Store in a cool, dry, well-ventilated area, away from sources of ignition and incompatibilities. Keep containers securely sealed when not in use. Containers that have been opened must be carefully resealed to prevent leakage. Indoor storage should meet OSHA standards and appropriate fire codes. Empty containers retain residue and may be dangerous.

### 7.3 Specific End Uses

For in vitro laboratory use. For professional use only

## SECTION 8: Exposure Controls/personal Protection

### 8.1 Control Parameters

This product, as supplied, does not contain hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.

### 8.2 Exposure Controls

#### Eye protection

Wear eye protection with side shields or goggles. Wear indirect-vent, impact and splash resistant goggles when working with liquids.

#### Skin Protection

Use of gloves approved to relevant standards made from the following materials may provide suitable chemical protection: PVC, neoprene, or nitrile rubber gloves. Suitability and durability of a glove is dependent on usage, e.g. frequency and duration of contact, chemical resistance of glove material, glove thickness, dexterity. Always seek advice from glove suppliers. Contaminated gloves should be replaced. Use of an apron and over-boots of chemically impervious materials such as neoprene or nitrile rubber. Launder soiled clothes or properly disposed of contaminated material, which cannot be decontaminated.

#### Respiratory protection

Not required under normal use.

#### Appropriate Engineering Controls

Showers  
Eyewash stations  
Ventilation Systems

None of the chemicals in Section 3 are regulated under "ACGIH\_carcinogen", "ACGIH\_Notations", "ACGIH\_TLV\_Basis", "ACGIHsmg", "ACGIHsppm", "ACGIHtmg", "ACGIHtppm", "CAN\_AL\_Carcinogen", "CAN\_AL\_Notation", "CAN\_ALsmg", "CAN\_ALsppm", "CAN\_ALtmg", "CAN\_ALtppm", "CAN\_ONsmg", "CAN\_ONsppm", "CAN\_ONtmg", "CAN\_ONtppm", "CAN\_QCVECDmg - CANADA\_QUEBEC VALEUR D'EXPOSITION DE COURTE DUREE\_mg", "CAN\_QCVECDppm - CANADA\_QUEBEC VALEUR D'EXPOSITION DE COURTE DUREE\_ppm", "CAN\_QCVEMPmg - CANADA\_QUEBEC VALEUR D'EXPOSITION MOYENNE PONDÉRIÉE\_mg", "CAN\_QCVEMPppm - CANADA\_QUEBEC VALEUR D'EXPOSITION MOYENNE PONDÉRIÉE\_ppm", "CANsmg", "CANSppm", "CANTmg", "CANTppm", "NIOSH\_carcinogen", "nioshsmg", "nioshsppm", "nioshtmg", "nioshtppm", "OSHA\_SkinDesignation", "OSHA\_Tables\_Z1\_Z2\_Z3", "OSHA\_Carcinogen - OSHA Carcinogen", "OSHAsmg", "OSHA\_sppm", "OSHAtmg", "OSHAtpm"

## SECTION 9: Physical and Chemical Properties

### 9.1 Information on Basic Physical and Chemical Properties

Density	1.0 g/mL
Specific Gravity	1.0
% VOC	No Data Available.
Density VOC	No Data Available.
% HAPS	No Data Available.
Density HAPS	No Data Available.
% VHAPS	No Data Available.
Density VHAPS	No Data Available.
% Solids By Weight	No Data Available.

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Appearance	Clear Liquid
Odor Threshold	N/A
Odor Description	Odorless to Weak Odor
pH	Near-neutral
Water Solubility	Soluble
Flammability	No Data Available.
Flash Point Symbol	No Data Available.
Flash Point	No Data Available.
Viscosity	No Data Available.
Lower Explosion Level	No Data Available.
Upper Explosion Level	No Data Available.
Vapor Pressure	No Data Available.
Vapor Density	No Data Available.
Freezing Point	No Data Available.
Melting Point	No Data Available.
Low Boiling Point	No Data Available.
High Boiling Point	No Data Available.
Auto Ignition Temp	No Data Available.
Decomposition Pt	No Data Available.
Evaporation Rate	No Data Available.
Coefficient Water/Oil	No Data Available.

### 9.2 Other Information

No additional information available.

## SECTION 10: Stability and Reactivity

### 10.1 Reactivity

No dangerous reactions known under normal conditions of use.

### 10.2 Chemical Stability

Stable under normal conditions

### 10.3 Possibility of Hazardous Reactions

#### Hazardous Reactions/Polymerization

None known to occur.

### 10.4 Conditions to Avoid

Heat. Incompatible materials.

### 10.5 Incompatible Materials

Strong bases, acids, and oxidizing agents.

### 10.6 Hazardous Decomposition Products

Oxides of carbon.

## SECTION 11: Toxicological Information

### 11.1 Information on Hazard Classes

#### Acute Toxicity

May be harmful in contact with skin

May be harmful if swallowed

The Acute Toxicity Estimate (ATE) for an oral exposure to this mixture is > 5000 mg/kg body weight

The Acute Toxicity Estimate (ATE) for a dermal exposure to this mixture is > 20,000 mg/kg body weight

The Acute Toxicity Estimate (ATE) for an inhalation (vapor) exposure to this mixture is >20 mg/l

#### Aspiration Hazard

Based on available data, the classification criteria are not met.

#### Carcinogenicity

Based on available data, the classification criteria are not met.

#### Germ Cell Mutagenicity

Based on available data, the classification criteria are not met.

#### Reproductive Toxicity

Based on available data, the classification criteria are not met.

#### Respiratory/Skin Sensitization

Based on available data, the classification criteria are not met.

#### Serious Eye Damage/Irritation

Based on available data, the classification criteria are not met.

#### Skin Corrosion/Irritation

Based on available data, the classification criteria are not met.

#### Specific Target Organ Toxicity - Repeated Exposure

Based on available data, the classification criteria are not met.

#### Specific Target Organ Toxicity - Single Exposure

Based on available data, the classification criteria are not met.

#### Likely Routes of Exposure

Inhalation, Ingestion, Skin contact, Eye contact

### 11.2 Information on Other Hazards

No additional information available.

## SECTION 12: Ecological Information

### 12.1 Toxicity

Based on available data, the classification criteria are not met.

### 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

No data available.

### 12.6 Endocrine Disrupting Properties

No data available.

### 12.7 Other Adverse Effects

No data available.

## SECTION 13: Disposal Considerations

### 13.1 Waste Treatment Methods

It is the responsibility of the user of the product to determine at the time of disposal whether the product meets local criteria for hazardous waste. Waste management should be in full compliance with national, state and local laws. Empty Containers retain product residue which may exhibit hazards of material, therefore do not pressurize, cut, glaze, weld or use for any other purposes.

## SECTION 14: Transportation Information

	U.S. DOT Information	IMDG Information	IATA Information	Canada TDG Information	ADR	ADN	RID
<b>14.1 UN Number:</b>	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Regulated	Not Regulated
<b>14.2 Proper shipping name:</b>	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
<b>14.3 Hazard Class:</b>	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
<b>14.4 Packing Group:</b>	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
<b>14.5 Environmental Hazards</b>	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
<b>14.6 Special Precautions for User:</b>	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
<b>14.7 Maritime Transport in Bulk According to IMO Instruments:</b>	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable

## SECTION 15: Regulatory Information

### 15.1 Safety, Health, and Environmental Regulations/legislation Specific for the Substance or Mixture

CAS	Chemical Name	% By Weight	Regulation List
0055965-84-9	2-Methyl-1,2-thiazol-3(2H)-one - 5-chloro-2-methyl-1,2-thiazol-3(2H)-one (1:1)	<0.04%	DSL,SARA312

### 15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

#### US State Regulation

California Proposition 65 – This product does not contain any substances known to the State of California to cause cancer, developmental and/or reproductive harm.

## SECTION 16) OTHER INFORMATION

### Glossary

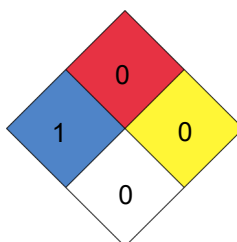
ACGIH - American Conference of Governmental Industrial Hygienists; CAS - Chemical Abstracts Service ; Chemtrec - Chemical Transportation Emergency Center; DSL - Domestic Substances List; ESL - Effects screening levels; GHS - "Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations; HMIS - Hazardous Material Information Service; IATA - Dangerous Goods Regulations (DGR) for the air transport (IATA); IMDG - International Maritime Dangerous Goods Code; LC - Lethal Concentration; LD - Lethal Dose; NFPA - National Fire Protection Association; OEL - Occupational Exposure Limits; OSHA- Occupational Safety and Health Administration, US Department of Labor; PEL - Permissible Exposure Limit; SARA 313 - Superfund Amendments and Reauthorization Act, Section 313; SCBA - Self Contained Breathing Apparatus; ppm - parts per million; STEL - Short-term exposure limit; TLV - Threshold Limit Value; TSCA - Toxic Substances Control Act Public Law 94-469; TWA - Time-weighted average; US DOT- US Department of Transportation.

#### HMIS

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Personal Protection  
(\* ) - Chronic effects

#### NFPA



Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks

#### Version 1.0:

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