

Safety Data Sheet (SDS)

OSHA HazCom 2012 Standard 29 CFR 1910.1200. Prepared to GHS Rev03.

Issued on 09/29/2016

1 Identification

- **Product identifier**
- **Trade name: Synovasure® Alpha Defensin ELISA Test Kit / Synovasure® Lateral Flow Test Control Kit**
 1. QC1 Alpha Defensins, lyophilized
 2. QC2 Alpha Defensins, lyophilized
 3. QC3 Alpha Defensins, lyophilized
 4. Calibrator Alpha Defensins, lyophilized
 5. Positive Control, Alpha Defensin LF
 6. Negative Control, Alpha Defensin LF
- **Product number:** P50002, P50003, P50004, P50005, P50026, P50027
- **Product description** 0.25 mL/vial, white lyophilized powder, odorless.
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**

CD Diagnostics, Inc.
650 Naamans Road
Suite 100
Claymont, DE 19703
302-367-7770
www.cddiagnostics.com
- **Emergency telephone number:** 1-800-535-5053(USA) 1-352-323-3500(International)

2 Hazard(s) identification

- **Classification of the substance or mixture**



May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labeling:**

2-methyl-2H-isothiazol-3-one
- **Hazard statements**

May cause an allergic skin reaction.
- **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapors/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
Contaminated work clothing should not be allowed out of the workplace.
Specific treatment (see on this label).
Wash contaminated clothing before reuse.
If skin irritation or rash occurs: Get medical advice/attention.
IF ON SKIN: Wash with plenty of water.
Dispose of contents/container in accordance with local/regional/national/international regulations.

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(Contd. of page 1)

Classification system:

- **NFPA ratings (scale 0 - 4)**



- **HMS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

2682-20-4	2-methyl-2H-isothiazol-3-one	≤ 2.5%
	Acute Tox. 3, H331; Skin Corr. 1A, H314; Eye Dam. 1, H318; Aquatic Acute 1, H400; Acute Tox. 4, H302; Skin Sens. 1, H317; STOT SE 3, H335	

4 First-aid measures

- **Description of first aid measures**
- **General information:**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.
In case of unconsciousness, place patient securely on side position for transportation.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Give large amounts of water. If symptoms persist consult doctor.
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required. (Contd. on page 3)

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(Contd. of page 2)

- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Precautions for safe handling**
Thorough dedusting.
Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:** 2°C to 8°C (35°F to 47°F)
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with occupational exposure limits:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Select glove material based on penetration times, rates of diffusion and degradation.
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

(Contd. on page 4)

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(Contd. of page 3)

· **Penetration time of glove material**

The exact break-through time has to be determined and observed by the manufacturer of the protective gloves.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Lyophilized powder

Color: White

· **Odor:** Odorless

· **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: Not determined.

Boiling point/Boiling range: Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not determined.

· **Ignition temperature:**

Decomposition temperature: Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

· **Vapor pressure:** Not applicable.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

Water: Insoluble.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

· **Solvent content:**

Organic solvents: 0.0 %

Solids content: 100.0 %

(Contd. on page 5)

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(Contd. of page 4)

- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Harmful

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

(Contd. on page 6)

SD1002 V1.1

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(Contd. of page 5)

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Non-Regulated Material
- **Packing group**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **UN "Model Regulation":** -

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

2682-20-4	2-methyl-2H-isothiazol-3-one
7778-77-0	potassium dihydrogenorthophosphate

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

(Contd. on page 7)

SD1002 V1.1

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(Contd. of page 6)

<ul style="list-style-type: none"> • Chemicals known to cause developmental toxicity:
None of the ingredients is listed.

<ul style="list-style-type: none"> • Carcinogenic categories • EPA (Environmental Protection Agency)
None of the ingredients is listed.

<ul style="list-style-type: none"> • TLV (Threshold Limit Value established by ACGIH)
None of the ingredients is listed.

<ul style="list-style-type: none"> • NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients is listed.

- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**

2-methyl-2H-isothiazol-3-one





- **Hazard statements**

May cause an allergic skin reaction.

- **Precautionary statements**

- Avoid breathing dust/fume/gas/mist/vapors/spray.
- Wear protective gloves/protective clothing/eye protection/face protection.
- Contaminated work clothing should not be allowed out of the workplace.
- Specific treatment (see on this label).
- Wash contaminated clothing before reuse.
- If skin irritation or rash occurs: Get medical advice/attention.
- IF ON SKIN: Wash with plenty of water.
- Dispose of contents/container in accordance with local/regional/national/international regulations.

<ul style="list-style-type: none"> • National regulations:
The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.

<ul style="list-style-type: none"> • State Right to Know 	
9067-32-7 Hyaluronic acid sodium salt	≤ 2.5%
2682-20-4 2-methyl-2H-isothiazol-3-one	≤ 2.5%
 Acute Tox. 3, H331;  Skin Corr. 1A, H314; Eye Dam. 1, H318;  Aquatic Acute 1, H400;  Acute Tox. 4, H302; Skin Sens. 1, H317; STOT SE 3, H335	≤ 2.5%
7778-77-0 potassium dihydrogenorthophosphate	≤ 2.5%
All ingredients are listed.	

(Contd. on page 8)

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(Contd. of page 7)

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Date of preparation / last revision** 09/29/2016

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

Acute Tox. 4: Acute toxicity, Hazard Category 4

Acute Tox. 3: Acute toxicity, Hazard Category 3

Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1