

Safety Data Sheet

according to 1907/2006/EC, Article 31

Issued on 2014.11.18

* SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: Synovasure® PJI 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
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.
- **Application of the substance / the mixture**


Intended for clinical use.
0.25 mL/vial, white lyophilized powder, odorless.
- **1.3 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
- **1.4 Emergency telephone number:** 1-352-323-3500 (InfoTrac)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

The product is not classified according to the CLP regulation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**

 Xn; Harmful

R20: Harmful by inhalation.
- **Hazard description:** Odourless
- **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Non-Regulated Material
- **Hazard pictograms** Non-Regulated Material
- **Signal word** Non-Regulated Material
- **Hazard statements** Non-Regulated Material
- **Precautionary statements** Precautionary statements
- **Additional information:**

Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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



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(Contd. of page 1)

SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 2682-20-4 EINECS: 220-239-6	2-methyl-2H-isothiazol-3-one  T R23;  C R35;  Xn R22;  Xi R37-41;  Xi R43;  N R50  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%
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- **Additional information:** For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 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. Keep patient warm. Consult doctor if symptoms persist.
In case of unconsciousness place patient stably in 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:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

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

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.

(Contd. on page 3)

SD1010 V1.0

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(Contd. of page 2)

See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**

Thorough dedusting.
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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 container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**

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 valid during the making were used as basis.
- **8.2 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.
- **Respiratory protection:** 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.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the 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.
- **Penetration time of glove material**

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

(Contd. on page 4)

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(Contd. of page 3)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Lyophilized powder

Colour: White

· **Odour:** Odourless

· **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: 390

Decomposition temperature: Not determined.

· **Self-igniting:** Product is not self-igniting.

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

· Explosion limits:

Lower: Not determined.

Upper: Not determined.

· **Vapour 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 %

· **9.2 Other information:** No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity:** No further relevant information available.

(Contd. on page 5)

SD1010 V1.0

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(Contd. of page 4)

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

SECTION 11: Toxicological information

- **11.1 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 the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Harmful

SECTION 12: Ecological information

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

SECTION 13: Disposal considerations

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

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Non-Regulated Material
- **14.2 UN proper shipping name**
- **ADR, ADN, IMDG, IATA** Non-Regulated Material

(Contd. on page 6)

SD1010 V1.0

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(Contd. of page 5)

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

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008** Non-Regulated Material
- **Hazard pictograms** Non-Regulated Material
- **Signal word** Non-Regulated Material
- **Hazard statements** Non-Regulated Material

· **National regulations:**

The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.

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

SECTION 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.

· **Relevant phrases**

- 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.

R22 Harmful if swallowed.

R23 Toxic by inhalation.

R35 Causes severe burns.

R37 Irritating to respiratory system.

R41 Risk of serious damage to eyes.

R43 May cause sensitisation by skin contact.

R50 Very toxic to aquatic organisms.

· **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

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

(Contd. on page 7)

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(Contd. of page 6)

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)

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 - Acute Hazard, Category 1

*** Data compared to the previous version altered.**