

## Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g), Rev. 2012 and GHS Rev 03.

Issued on 25.07.2017

### \* 1 Identification

• **Product identifier**

• **Trade name: Synovasure Alpha Defensin Lateral Flow Dropper Bottle & Synovasure Control Reconstitution Bottle**

• **Product description**

**Product:** Synovasure® Alpha Defensin Lateral Flow Dropper Bottle, 2-5mL of buffer

**Product #:** P50025

**Product:** Synovasure® Control Reconstitution Bottle, 2mL of Solution

**Product #:** P50028

• **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:** InfoTrac: 1-800-535-5053 (USA), 1-352-323-3500 (International)

### 2 Hazard(s) identification

• **Classification of the substance or mixture**

The product is not classified according to the Globally Harmonized System (GHS).

• **Hazard description:** Odorless

• **Information concerning particular hazards for human and environment:**

The product has to be labeled due to the calculation procedure of international guidelines.

• **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

• **Label elements**

• **GHS label elements** Non-Regulated Material

• **Hazard pictograms** Non-Regulated Material

• **Signal word** Non-Regulated Material

• **Hazard statements** Non-Regulated Material

• **Classification system:**

• **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

• **HMIS-ratings (scale 0 - 4)**



HEALTH 0 Health = 0

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.

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<ul style="list-style-type: none"> <li><b>Dangerous Components:</b></li> </ul>		
2682-20-4	2-methyl-2H-isothiazol-3-one	≤ 0.1%
	<ul style="list-style-type: none"> <li>☠ 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</li> </ul>	

### 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:**

CO<sub>2</sub>, 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:**

As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

### 6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures** Not required.

- Environmental precautions:** Dilute with plenty of water.

- Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (ie. sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

Dispose of the collected material according to regulations.

- 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**

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- Information about protection against explosions and fires:** No special measures required.

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- **Conditions for safe storage, including any incompatibilities**
- **Storage: 2°C to 30°C (35°F to 86°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.
- **Eye protection:** Goggles recommended during refilling.

### \* 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
  - **Form:** Liquid
  - **Color:** Varies
- **Odor:** Odorless
- **Odor threshold:** Not determined.
- **pH-value:** 7.4 (P50025); 4.5 (P50028)
- **Change in condition**
  - **Melting point/Melting range:** Not determined.
  - **Boiling point/Boiling range:** Not determined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not applicable.
- **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 determined.

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- **Density:** Not determined.
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with Water:** Fully miscible.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - Dynamic:** Not determined.
  - Kinematic:** Not determined.
- **Solvent content:**
  - Organic solvents:** 0.0 %
  - Other information** No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Product is stable under normal conditions.
- **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.
  - **Additional toxicological information:** There is no data available for this product

#### · **Carcinogenic categories**

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

· **NTP (National Toxicology Program)**

None of the ingredients are listed.

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

None of the ingredients are 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

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- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 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.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

### \* 14 Transport information

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

### \* 15 Regulatory information

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

• <b>Section 355 (extremely hazardous substances):</b>
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None of the ingredients are listed.
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• <b>Section 313 (Specific toxic chemical listings):</b>
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None of the ingredients are listed.
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• <b>TSCA (Toxic Substances Control Act):</b>
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All ingredients are listed.
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• <b>Proposition 65</b>
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• <b>Chemicals known to cause cancer:</b>
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None of the ingredients are listed.
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• <b>Chemicals known to cause reproductive toxicity for females:</b>
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None of the ingredients are listed.
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• <b>Chemicals known to cause reproductive toxicity for males:</b>
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None of the ingredients are listed.
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<ul style="list-style-type: none"> <li>· <b>Chemicals known to cause developmental toxicity:</b></li> </ul>
<p>None of the ingredients are listed.</p>
<ul style="list-style-type: none"> <li>· <b>Carcinogenic categories</b></li> </ul>
<ul style="list-style-type: none"> <li>· <b>EPA (Environmental Protection Agency)</b></li> </ul>
<p>None of the ingredients are listed.</p>
<ul style="list-style-type: none"> <li>· <b>TLV (Threshold Limit Value established by ACGIH)</b></li> </ul>
<p>None of the ingredients are listed.</p>
<ul style="list-style-type: none"> <li>· <b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b></li> </ul>
<p>This product is listed as a hazardous material under criteria of the Federal OSHA Hazard Communication Standard, 29 CFR 1910.1200</p>
<ul style="list-style-type: none"> <li>· <b>GHS label elements</b> Non-Regulated Material</li> <li>· <b>Hazard pictograms</b> Non-Regulated Material</li> <li>· <b>Signal word</b> Non-Regulated Material</li> <li>· <b>Hazard statements</b> Non-Regulated Material</li> </ul>
<ul style="list-style-type: none"> <li>· <b>National regulations:</b></li> </ul>
<p>The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.</p>
<ul style="list-style-type: none"> <li>· <b>State Right to Know</b></li> </ul>
<p>All ingredients are listed.</p>
<ul style="list-style-type: none"> <li>· <b>Chemical safety assessment:</b> A Chemical Safety Assessment has not been carried out.</li> </ul>

### 16 Other information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Date of preparation / last revision** 11/9/2016 / 1

· **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 - Acute Hazard, Category 1

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

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