

Safety Data Sheet

according to 1907/2006/EC, Article 31


Revision: 25.07.2017

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

- **1.1 Product identifier:**
- **Trade name: Synovasure Alpha Defensin Lateral Flow Dropper Bottle & Synovasure Control Reconstitution Bottle**
- **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:**
Product: Synovasure® Alpha Defensin Lateral Flow Dropper Bottle, 2-5mL of buffer Product #: P50025

Product: Synovasure® Control Reconstitution Bottle, 2mL of Solution
Product #: P50028
- **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:** InfoTrac 1-352-323-3500

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
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

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



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

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· Dangerous components:		
CAS: 2682-20-4 EINECS: 220-239-6 RTECS: NX8157080	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%

- **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:**

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.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Not required.

· 6.2 Environmental precautions:

Dilute with plenty of water.

· 6.3 Methods and material for containment and cleaning up:

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

Dispose contaminated materials as waste according to item 13.

Ensure adequate ventilation.

Dispose of the material collected according to regulations.

· 6.4 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.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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 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:**
- **Material of gloves:** Not required.
- **Penetration time of glove material:** Not applicable.
- **Eye protection:** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

• Form:	Liquid
• Colour:	Varies
• Odour:	Odourless
- **pH-value:** 7.4 (P50025); 4.4 (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.
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- **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 determined.
- **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 %
- **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

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

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

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

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
- **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.

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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 Harmonised System of Classification and Labelling of Chemicals

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 - AcuteHazard, Category 1