


**Section 1 – Identification**

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| <b>Product Name</b>                      | Stool Bacterial Pathogens Panel (SBPP)   |
| <b>Catalog/Part Number(s)</b>            | 02394-001-00<br>02394-101-00<br>300780   |
| <b>Brand</b>                             | Great Basin Scientific   |
| <b>Manufacturer/Supplier Information</b> | Vela Operations USA<br>2441 South 3850 West<br>Salt Lake City, UT 84120<br>US Phone: 1-888-320-7636<br>gb.support@veladx.com |
|  | <b>EU Representative</b><br>Vela Diagnostics Germany GmbH<br>Albert-Einstein-Ring 15<br>22761 Hamburg, Germany               |
| <b>Emergency Phone Number</b>            | Technical Support: 1.888.320.7636<br>(6AM to 6PM Mountain Time)  |
| <b>Recommended Use</b>                   | In vitro diagnostic medical device for laboratory use.   |

**Section 2 – Hazard(s) Identification**

|   |   |
|---|---|
| <b>Classification of Substances or Mixtures as per (EC) 1272/2008 (GHS)</b> | This SDS is intended for the fully assembled assay cartridge which contains both liquid and dried reagent mixtures.   |
| <b>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)</b>         | Skin Irritant (Category 2); H315-Causes skin irritation<br>Eye Irritant (Category 2); H319-Causes serious eye irritation<br>Skin Sensitization (Category 1); H317-May cause an allergic skin reaction   |
| <b>Signal Word</b>  | Warning   |
| <b>Label Elements</b>   |    |
| <b>Hazard Statements</b>  | None identified.  |
| <b>Precautionary Statements</b>   |   |
| <b>Prevention</b>   | Avoid release to the environment. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.  |
| <b>Response</b>   | IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor/physician if you feel unwell.<br>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.<br>IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. |

**Storage**

Not available.

**Disposal**

Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

**Section 3 – Composition/Information on Ingredients****Substances**

Material does not meet the criteria of a substance.

**Mixtures**

| Chemical Name   | Identifiers                                  | Concentration | Classifications |
|---|--|---------------|-----------------|
| 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) | CAS-No. 55965-84-9<br>Index No. 613-167-00-5 | 0.01%-0.6%    | See Section 11  |
| Modified alkyl carboxylate  |  | 0.01%-0.6%    | See Section 11  |

All other components are below reportable levels. The specific chemical identity and/or exact percentage of composition of mixtures has been withheld as a trade secret.

**Section 4 – First Aid Measures****Eyes**

First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. May cause eye irritation. IF IN EYES: Immediately rinse with water for 2-3 minutes. After initial rinse, if present and possible, remove contact lenses. Continue rinsing. Consult physician.

**Skin**

First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. May cause skin irritation or rash. IF ON SKIN: Wash affected area with soap and water. Consult physician if irritation or rash persists.

**Ingestion**

First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor/physician if you feel unwell.

**Inhalation**

First aid is not expected to be necessary if material is used under ordinary conditions and as recommended. Move the person to fresh air. If breathing difficulty is observed, consult a physician.

**Chronic/Delayed Effects**

No information available.

**Notes for Physician**

Treat symptomatically.

**Section 5 – Fire Fighting Measures****Suitable Extinguishing Media**Water, foam, dry powder or CO<sub>2</sub> are all acceptable**Unsuitable Extinguishing Media**

No data available.

**Specific Hazard Arising from Chemical During Fire**

Gases hazardous to health may be formed during combustion of the plastic cartridge components.

**General Fire Hazards**

No known unusual fire or explosion hazards.

**Protective Equipment and Precautions for Firefighters**

Wear protective clothing and self-contained breathing apparatus as necessary.

**Section 6 – Accidental Release Measures****Spills and Leaks**

Wear appropriate protective clothing while handling and during clean-up. In the event of a cartridge leak, absorb any spilled material with an absorbent wipe or absorbent material. Spilled material and damaged cartridge and should be disposed of in accordance with local, State and Federal regulations. Ensure adequate ventilation. Also refer to Section 13 for additional information on disposal considerations.

**Emergency Procedures**

No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended.

**Section 7 – Handling and Storage****Precautions for Safe Handling**

No special handling necessary. Wear appropriate personal protective equipment for the laboratory setting. If cartridge is broken, avoid contact with spilled reagents. Avoid contact with eyes and skin. Avoid ingestion or inhalation. When using, do not eat, drink or smoke.

**Precautions for Safe Storage**

Store in accordance with product labeling.

**Section 8 - Exposure Controls/Personal Protection****Eyes**

Use protective eye wear and shield as appropriate. Follow institution's instruction guidelines for handling chemicals.

**Skin**

Follow institution guidelines for handling chemical in a laboratory setting.

**Clothing**

Wear appropriate clothing to prevent skin exposure.

**Respirator**

None required when used in prescribed manner.

**Occupational Exposure Limits**

None identified.

**Engineering Controls**

None identified.

**Section 9 – Physical and Chemical Properties****Appearance****Form**

Molded plastic consumable cartridge with multiple liquid filled, foil blister packs attached.

**Physical State**

Solid

**Color**

Black plastic cartridge with opaque silver blister packs attached. Blister packs contain colorless to light amber/brown or light blue clear aqueous solutions.

**Odor**

No data available.

**Odor Threshold**

No data available.

**pH**

All cartridge reagents are pH 7.0 - 9.0.

**Melting Point/Freezing Point**

No data available.

**Initial Boiling Point**

No data available.

**Flash Point**

No data available.



|   |  |
|---|--|
| <b>Evaporation Rate</b>                             | No data available.                                     |
| <b>Flammability (solid/gas)</b>                     | No data available.                                     |
| <b>Upper/Lower Flammability or Explosive Limits</b> | No data available.                                     |
| <b>Vapor Pressure</b>                               | No data available                                      |
| <b>Vapor Density</b>                                | No data available.                                     |
| <b>Relative Density</b>                             | No data available.                                     |
| <b>Solubility</b>                                   | All component reagents and mixtures are water soluble. |
| <b>Partition Coefficient</b>                        | No data available.                                     |
| <b>Auto-ignition Temperature</b>                    | No data available.                                     |
| <b>Decomposition Temperature</b>                    | No data available.                                     |
| <b>Viscosity</b>                                    | No data available.                                     |

#### Section 10 – Stability and Reactivity

|   |   |
|---|---|
| <b>Chemical Stability</b>                     | The product is stable and non-reactive under specified storage and normal use conditions.   |
| <b>Conditions to Avoid</b>                    | Store in accordance with package instructions. Burning of cartridge and/or reagents may liberate toxic byproducts.  |
| <b>Incompatibilities with Other Materials</b> | None identified.  |
| <b>Hazardous Decomposition Products</b>       | Burning of cartridge and/or reagents may liberate toxic byproducts. Hazardous decomposition products formed under fire conditions may include: Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas. |
| <b>Hazardous Polymerization</b>               | Will not occur.   |
| <b>Possibility of Hazardous Reactions</b>     | None identified.  |
| <b>Reactivity</b>                             | No dangerous reactions identified under normal use.   |

#### Section 11 – Toxicological Information

##### Hazardous ingredients according to Regulation (EC) No 1272/2008

| Chemical Component (Trade Name)  | Identifiers            | Concentration Limits | Classifications   |
|--|------------------------|----------------------|---|
| 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (ProClin® 300) | CAS-No. 55965-84-9     | >= 0.6% - < 5%       | Acute Tox. 3; Skin Corr. 1B; Skin Sens. 1; Aquatic Acute 1; Aquatic Chronic 1; H301, H331, H311, H314, H317, H400, H410 |
|  | Index No. 613-167-00-5 | 0.06% - < 0.6%       | Skin Irritant. 2, H315; Eye Irritant. 2, H319   |
|  |                        | >= 0.0015%           | Skin Sens. 1, H317  |
| Modified alkyl carboxylate   |                        | >= 5% - < 10%        | Aquatic Chronic 4; H413   |


**Acute Toxicity**

| Chemical Component Name<br>(Trade Name)  | Acute Toxicity   |
|--|--|
| 5-Chloro-2-methyl-4-isothiazolin-3-one<br>and 2-methyl-2H-isothiazol-3-one (3:1)<br>(ProClin® 300) | LD50 Oral - Rat - 862 mg/kg<br>LD50 Dermal - Rabbit - 2,800 mg/kg  |
| <b>Inhalation</b>  | No data available.   |
| <b>Skin Sensitization</b>  | Skin Sensitization 1   |
| <b>Skin Irritation</b>   | Skin Irritant 2  |
| <b>Eye Damage/ Irritation</b>  | Eye Irritant 2   |
| <b>Repeat Dose Toxicity</b>  | No data available.   |
| <b>Reproductive and Developmental Toxicity</b>   | No data available. None of the reagents in the product have been identified as having association with infertility or birth defects.   |
| <b>Mutagenicity and Carcinogenicity</b>  | No data available. No component of this product at levels greater than or equal to 0.1% is identified as probable, possible, potential, anticipated or confirmed human carcinogen by IARC, NTP, or OSHA. |

**Section 12 – Ecological Information**

|   |   |
|---|---|
| <b>Bioaccumulation Potential</b>          | No data available   |
| <b>Aquatic Toxicity</b>                   | No data available. Chemical components of the product have known aquatic toxicity at concentrations greater than the concentrations used in this product. See section 11. |
| <b>Persistence and Degradability</b>      | No data available.  |
| <b>Ecotoxicity Effects</b>                | No data available.  |
| <b>Mobility in Soil</b>                   | No data available.  |
| <b>Results of PBT and vPvB Assessment</b> | No PBT/vPvB assessment has been conducted.  |
| <b>Other Adverse Effects</b>              | No data available.  |

**Section 13 – Disposal Considerations**

|                      |  |
|----------------------|--|
| <b>Product Waste</b> | <p>UNUSED: Dispose of unused product in accordance with regulations governed by institutional environmental waste disposal procedures and guidelines for aqueous, non-toxic solutions. Users outside of the United States should check for country or regional regulations. Do not allow this material to drain into sewers/water supplies.</p> <p>USED: Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents and disposal requires standard precautions. Used product should be disposed of as directed in use instructions and according to your institution's waste procedures for proper disposal of used biological materials. If national or regional regulations do not provide clear direction</p> |
|----------------------|--|



|                           |   |
|---------------------------|---|
|                           | on proper disposal, biological specimens and used cartridges should be disposed per WHO (World Health Organization) medical waste handling and disposal guidelines. Do not allow this material to drain into sewers/water supplies. |
| <b>Packaging Waste</b>    | No special considerations. Dispose of packaging material in accordance with regulations governed by institutional waste disposal procedures.  |
| <b>RCRA Series Wastes</b> | None of the components in this product are RCRA U/P Series Wastes.  |

**Section 14 – Transport Information**

|   |   |
|---|---|
| <b>Proper Shipping</b>                            | This product is not regulated as a hazardous material.  |
| <b>Transport</b>                                  | Transport of this material should be done in compliance with all federal, state and local regulations. This product has been identified as regulated as dangerous goods by US DOT, IMDG, or IATA. |
| <b>UN Number</b>                                  | Not applicable.   |
| <b>UN Proper Shipping Name</b>                    | Not applicable.   |
| <b>Transport Hazard Classes and Packing Group</b> | Not applicable.   |
| <b>Environmental Hazards</b>                      | Not identified.   |

**Section 15 – Regulatory Information**

|  |   |
|--|---|
| <b>OSHA Hazardous</b>                                | None identified.  |
| <b>National Fire Protection Agency (NFPA) Rating</b> | Not applicable.   |
| <b>WHMIS Classification</b>                          | Not listed.   |
| <b>TSCA Status</b>                                   | Not listed.   |
| <b>SARA Section 302</b>                              | No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.   |
| <b>SARA Section 313</b>                              | Not listed. This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313. |
| <b>SARA Section 311/312</b>                          | Not listed.   |
| <b>Massachusetts Right to Know Components</b>        | Not listed.   |
| <b>California Prop. 65 Components</b>                | This product is not known to contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.   |
| <b>Pennsylvania Right to Know Components</b>         | Not listed.   |
| <b>New Jersey Right to Know Components</b>           | Not listed.   |

**Section 16 – Other Information****Issue Date** July 2019**Revision Number** 00**Revision History**

| Revision | Description      |
|----------|------------------|
| 00       | Initial release. |

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