



Section 1 – Identification

Product Name	GBS Assay (GBS)
Catalog/Part Number(s)	01683-001-00 300781
Brand	Great Basin Scientific
Manufacturer/Supplier Information	Vela Operations USA 2441 South 3850 West Salt Lake City, UT 84120 US Phone: 1-888-320-7636 gb.support@veladx.com
	EU Representative Vela Diagnostics Germany GmbH Albert-Einstein-Ring 15 22761 Hamburg, Germany
Emergency Phone Number	Technical Support: 1.888.320.7636 (6AM to 6PM Mountain Time)
Recommended Use	In vitro diagnostic medical device for laboratory use.

Section 2 – Hazard(s) Identification

Classification of Substances or Mixtures as per (EC) 1272/2008 (GHS)	This SDS is intended for the fully assembled assay cartridge which contains both liquid and dried reagent mixtures.
GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)	Skin Irritant (Category 2); H315-Causes skin irritation Eye Irritant (Category 2); H319-Causes serious eye irritation Skin Sensitization (Category 1); H317-May cause an allergic skin reaction
Signal Word	Warning
Label Elements	
Hazard Statements	None identified.
Precautionary Statements	
Prevention	Avoid release to the environment. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.
Response	IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor/physician if you feel unwell. 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. 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 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 CO₂ 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.
Evaporation Rate	No data available.



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

Section 10 – Stability and Reactivity

Chemical Stability	The product is stable and non-reactive under specified storage and normal use conditions.
Conditions to Avoid	Store in accordance with package instructions. Burning of cartridge and/or reagents may liberate toxic byproducts.
Incompatibilities with Other Materials	None identified.
Hazardous Decomposition Products	Burning of cartridge and/or reagents may liberate toxic byproducts. Hazardous decomposition products formed under fire conditions may include: Carbon oxides, Nitrogen oxides (NO _x), Sulphur oxides, Hydrogen chloride gas.
Hazardous Polymerization	Will not occur.
Possibility of Hazardous Reactions	None identified.
Reactivity	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 (Trade Name)	Acute Toxicity
5-Chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (ProClin® 300)	LD50 Oral - Rat - 862 mg/kg LD50 Dermal - Rabbit - 2,800 mg/kg
Inhalation	No data available.
Skin Sensitization	Skin Sensitization 1
Skin Irritation	Skin Irritant 2
Eye Damage/ Irritation	Eye Irritant 2
Repeat Dose Toxicity	No data available.
Reproductive and Developmental Toxicity	No data available. None of the reagents in the product have been identified as having association with infertility or birth defects.
Mutagenicity and Carcinogenicity	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

Bioaccumulation Potential	No data available
Aquatic Toxicity	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.
Persistence and Degradability	No data available.
Ecotoxicity Effects	No data available.
Mobility in Soil	No data available.
Results of PBT and vPvB Assessment	No PBT/vPvB assessment has been conducted.
Other Adverse Effects	No data available.

Section 13 – Disposal Considerations

Product Waste	<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>
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	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.
Packaging Waste	No special considerations. Dispose of packaging material in accordance with regulations governed by institutional waste disposal procedures.
RCRA Series Wastes	None of the components in this product are RCRA U/P Series Wastes.

Section 14 – Transport Information

Proper Shipping	This product is not regulated as a hazardous material.
Transport	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.
UN Number	Not applicable.
UN Proper Shipping Name	Not applicable.
Transport Hazard Classes and Packing Group	Not applicable.
Environmental Hazards	Not identified.

Section 15 – Regulatory Information

OSHA Hazardous	None identified.
National Fire Protection Agency (NFPA) Rating	Not applicable.
WHMIS Classification	Not listed.
TSCA Status	Not listed.
SARA Section 302	No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA Section 313	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.
SARA Section 311/312	Not listed.
Massachusetts Right to Know Components	Not listed.
California Prop. 65 Components	This product is not known to contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.
Pennsylvania Right to Know Components	Not listed.
New Jersey Right to Know Components	Not listed.

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

Revision	Description
00	Initial release.

Disclaimer/Statement of Liability

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