



AutoGenomics

SAFETY DATA SHEET

Follows OSHA GHS/ EU 2015/830, CLP 1272/2008

Section 1: IDENTIFICATION

Product identifier: Bacterial Vaginosis Positive Controls

Catalog Number: See Appendix 1

Recommended Use: For use in Laboratories. Refer to Product Insert or Application Notes.

Manufacturer: **AutoGenomics, Inc.**
1600 Faraday Ave.
Carlsbad, CA 92008

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Emergency Telephone: **1-866-782-8639**

Section 2: HEALTH HAZARD INFORMATION

OSHA/HCS Status: There are no known hazards identified with this mixture. However, the plasmid may contain a gene necessary for a bacterium to become antibiotic resistant.

While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains information for the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

GHS- Classification: The product is classified and labeled according to the Globally Harmonized System (GHS)

GHS label element: No label, signal word, or hazard statement. Not hazardous.

Precautionary Statement:

1. Acute Overexposure: May cause skin, eye or respiratory irritation upon contact.
2. Chronic Overexposure: Allergic reactions may develop in certain sensitive individuals.

Medical Conditions Aggravated by Exposure:

Allergy-prone and asthmatic individuals should be particularly cautious with enzymes and other materials of biologic origin
Do not ingest. Immediately call doctor if ingested.
If skin irritation occurs: Wash with plenty of water and seek medical advice/attention.
Wear protective gloves and wash thoroughly after handling.
If in eyes: Rinse with water for several minutes. Remove contact lenses, if present. Call doctor if any adverse reactions occur.



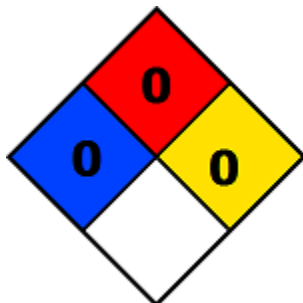
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Other hazards: None known.

NPFA



HMIS

Health	0
Flammability	0
Reactivity	0

Section 3: COMPOSITION/ INFORMATION ON INGREDIENTS

Substances/ Mixtures: Mixture

Components	CAS Number	% Wt.
EDTA	6381-92-6	0.04%
HCl	7647-01-0	0.05%
Plasmid DNA	NA	Proprietary
Tris Base	77-86-1	0.12%

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment.

Section 4: FIRST AID MEASURES

Description of first aid measures

- Eye Contact: Immediately flush eyes with copious amounts of water for at least 15 minutes; seek medical attention; and remove any contact lenses. Call a physician. If symptoms such as redness and irritation persist, obtain medical attention.
- Inhalation: If inhaled, remove to fresh air.
- Skin contact: In case of contact, immediately wash skin with soap and copious amounts of water.
- Ingestion: Do not ingest. If swallowed, wash out mouth with water provided the person is conscious. Never give anything by mouth to an unconscious person. Call a physician.

Section 5: FIRE and EXPLOSION INFORMATION

Extinguishing media:

Suitable extinguishing media: Use water spray, dry chemical or carbon dioxide, or foam

Special hazards arising from the substance or mixture: No specific fire hazard

Advice for firefighters: No special measures are required.



Section 6: ACCIDENTAL RELEASE MEASURES

Use of Personal Precaution, Protective Equipment and Emergency Procedures

Wear appropriate protective equipment for cleanup. See section 8.

Environmental precautions

Do not let product enter drains.

Methods and Materials Used for Containment and Cleanup procedures

Soak up with inert absorbent material. Use a 10% bleach solution in a well-ventilated area to disinfect. Place in a waste disposal container in compliance with national/state regulations.

Section 7: HANDLING AND STORAGE

Precaution for safe handling

Avoid contact with eyes, skin and clothing. Avoid inhalation. Use appropriate personal protective equipment.

Advice on General Occupational Hygiene:

Eating, drinking and smoking should be prohibited in areas where this material is handled stored and processed. Follow good industrial hygiene practices and wash hands after handling.

Recommendations on the condition for safe storage, including any incompatibilities

Store in the original container according to the labeling.

Section 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Control Parameters

Exposure Limits or threshold limits: None

Engineering Controls: No special ventilation is required.

Personal Protective Equipment

Wear appropriate equipment and clothing for laboratory use. Wear gloves to protect product, not hazardous for user unless allergic.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear colorless liquid
Flammability or Explosive Limits:	Not flammable or explosive
Odor	No odor
Vapor pressure	Not determined
Odor threshold	Not determined
Vapor density	Not determined
pH	Not determined



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Relative density	Not determined
Melting point/ freezing point	Not determined
Solubility	Not determined
Initial boiling point and boiling range	Not determined
Flash point	Not determined
Evaporation rate	Not determined
Flammability (solid, gas)	Not flammable
Partition coefficient: n-octanol/water	Not determined
Auto-ignition temperature	Product is not self-igniting
Decomposition temperature	Not determined
Viscosity	Not determined

Section 10: STABILITY AND REACTIVITY

Reactivity	Not determined
Chemical Stability	The product is stable under normal conditions.
Possibility of Hazardous reactions	Hazardous reactions will not occur under normal conditions and use.
Conditions to avoid	Oxidizing agents and excessive heat.
Incompatible material	Not determined
Hazardous decomposition products	Hazardous decomposition or by products will not occur under normal conditions

Section 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity:	There is no data available
Irritation/ Corrosion:	There is no data available
Sensitization	There is no data available
Carcinogenicity	No component greater than or equal to 0.1% that is potential or confirmed as a human carcinogen.
Specific target organ toxicity (single exposure):	There is no data available
Specific target organ toxicity (repeated exposure):	There is no data available
Aspiration hazard	There is no data available

Information on the likely routes of exposure: Dermal contact, eye contact and ingestion.

Potential acute health effects: No known significant effects or critical hazards.
Symptoms related to the physical, chemical and toxicological characteristics
No known significant effects or critical hazards.

Delayed and Immediate Effects and also Chronic Effects from short and long term exposure:

Short term	No known significant effects or critical hazards.
Long term	No known significant effects or critical hazards.



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Potential chronic health effects	May be harmful if inhaled, swallowed, absorbed through skin or if contacted by the eyes. May cause eye irritation.
Numerical measures of toxicity	No known significant effects or critical hazards.
Acute toxicity estimates	There is no data available

Section 12: ECOLOGICAL INFORMATION

Toxicity	No data available
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Mobility in soil	No data available
Results of PBT and vPvB assessment	No data available
Other adverse effects	None known.

Section 13: DISPOSAL CONSIDERATIONS

Waste Disposal Method

- Follow federal, state and local government requirements for disposal.
- US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3.

Section 14: TRANSPORTATION INFORMATION

<u>UN number and proper shipping name</u>	Not regulated
<u>TDG Class:</u>	Not regulated.
<u>US DOT</u>	Not a dangerous good.
<u>IATA</u>	Not a dangerous good.
Environmental hazards:	Not a dangerous good.
Any special precautions for user:	No special precautions.

Section 15: REGULATORY INFORMATION

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

U.S. Federal Regulations:

OSHA: No known OSHA hazards.

SARA 302, 311/312, 313 & 355: None of the ingredients are listed. No SARA Hazards

TSCA (Toxic Substances Control Act): This product is not regulated.

Clean Water Act (40 CFR 122.21 and 122.42): This product does not contain substances regulated as pollutants.

Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs) (40 CFR 61)

CERCLA (Comprehensive Environmental Response Compensation and Liability Act) (40 CFR 302) or SARA (40 CFR 355)



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This material does not contain any substances regulated as hazardous substances. There may be specific reporting requirements at the local, regional, or state level pertaining to release of this material.

U.S. State Regulations

Pennsylvania and New Jersey Right To Know Components

Deoxyribonucleic acids, plasmid DNA CAS No. 9007-49-2

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

International Regulations

Mexico – Minimum Risk, Grade 0

Canada – This SDS contains all the information required by the Controlled Products Regulations (CPR).

WHMIS Classification:

Not a toxic substance.

Section 16: OTHER INFORMATION

This material is not intended for food, household, agricultural or cosmetic use. The information in this SDS is correct to the best of our knowledge. Users should make independent decisions regarding completeness of the information based on all sources available. AutoGenomics shall not be held liable for reliance on the information provided in this SDS and/or any damage resulting from the handling or contact with the above named products.

Key Legend Information:

N/A – Not Applicable

ND – Not Determined

Prepared by Regulatory Affairs, AutoGenomics, Inc.

Rev	Change	CO #	Effective Date
A	Initial Doc with GHS and EU standards	3952	August 2017



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APPENDIX 1

Product Name	Catalog Number
BV QUAD Controls Combo Pack	12-0190-00
Bacteroides fragilis (BF) Positive Control	12-0220-00
Mobiluncus mulieris (MM) Positive Control	12-0230-00
Atopobium vaginae (AV) Positive Control	12-0240-00
Gardnerella vaginalis (GV) Positive Control	12-0250-00
Mobiluncus curtisii (MC) Positive Control	12-0260-00
Prevotella bivia (PB) Positive Control	12-0270-00

End of SDS