

SAFETY DATA SHEET

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Section 1 – PRODUCT AND COMPANY IDENTIFICATION

| PRODUCT NAME: | ePlex BCID-FP Control M320 |
|----------------|----------------------------|
| SYNONYMS: | N/A |
| PRODUCT CODES: | M320 |

USE OF THE SUBSTANCE PREPARATION: The ePlex BCID-FP Control M320 is intended for *in vitro* use as a qualitative external quality control to monitor the amplification, detection and identification steps of the ePlex[®] Blood Culture Identification Fungal Pathogen (BCID-FP) Panel performed on the ePlex System (GenMark Diagnostics, Inc.).

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET AND MANUFACTURER NAME AND ADDRESS:

Maine Molecular Quality Controls, Inc (MMQCI) 23 Mill Brook Road Saco, Maine 04072 (USA) E-mail: info@mmqci.com www.mmqci.com Emergency telephone number: 207-885-1072 Manufacturer Phone Number 207-885-1072

Manufacturer Fax Number 207-885-1079

Section 2 – HAZARD(S) IDENTIFICATION

HAZARDOUS INGREDIENTS:

23% Ethyl Alcohol

Classification: Void

This product is not considered to be flammable under ordinary laboratory conditions based on studies performed by MMQCI.

Section 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Characterization (Hazardous Chemical Ingredients):

| Chemical Name | EC-No. | Index-No | | 0/ | Classification | Labeling |
|----------------------|-----------|--------------|---------|--------|----------------|----------|
| Chemical Name EC-NO. | index-ino | CAS-No. | % | Symbol | R-Phrases | |
| Ethyl Alcohol | 200-578-6 | 603-002-00-5 | 64-17-5 | 23 | None | None |

Dangerous Components According to EC Criteria: None

Section 4 – FIRST AID MEASURES

General: No emergency care is anticipated.

In all cases of doubt or when symptoms occur, do the following:

Inhalation: Remove affected person to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Ingestion: Rinse mouth with water. Seek medical attention if signs of toxicity occur.

- Skin: Remove contaminated clothing. Wash affected area with plenty of soap and water. Seek medical attention if irritation develops.
- Eyes: Rinse immediately with plenty of water. Remove contact lenses if worn. Seek medical attention if redness or irritation develops.



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Section 5 – FIRE FIGHTING MEASURES

Flash Point (Method Used): Flammable Limits: Extinguishing Media: Auto-ignition Temperature: Special Fire Hazards: Explosion Hazards: 32°C (90°F) (ethanol vapor), Closed Cup N/A CO₂ or Dry Chemical / ABC Fire Extinguisher or water 363°C (ethanol vapor) N/A N/A

Section 6 – ACCIDENTAL RELEASE MEASURES

| Dama and Dava at | | | | | the static term | |
|--|----------|--|--|--|---|------------------------------------|
| Personal Precaution | ons: | | | Wear appropriate protecti | ive ciotning. | |
| Steps to be Taken in Case Material is Released or Spilled: | | Spilled: | Wipe up with appropriate absorbent material. | | | |
| Waste Disposal Method: Normal disposal container | | | | | | |
| | | Section | 7 – HANDL | ING AND STORAGE | | |
| Handling: | Handle p | per package insert instructi | ions. | | | |
| Storage: | Store at | 2°- 8°C. Do not freeze. | | | | |
| | S | Section 8 – EXPOSU | | ROLS / PERSONAL PI | ROTECTION | |
| Exposure Limit Va | lues: | None | | | | |
| Exposure Controls | 5: | This product is not expect should be equipped with | | | . Facilities storing or using this | s product |
| PERSONAL PROTI | ECTIVE I | EQUIPMENT: | | | | |
| Respiratory Protect Skin Protection: Ventilation: | tion: | None required Lab coat, gloves Normal | Work / | otection: Hygiene Practices: Protective Equipment: | Safety glasses Standard laboratory prec None required | autions |
| | | Section 9 – PH | SICAL AN | D CHEMICAL PROPE | ERTIES | |
| Component: Boiling Point: Melting Point: Vapor Density (AIR Vapor Pressure (m Appearance: | | Ethanol (23%) 86°C (186.8°F) N/A N/A N/A Liquid, colorless | | Specific Gravi Evaporation R Solubility in W pH: Odor: | ate (Butyl Acetate = 1): | N/A N/A Yes N/A Fruity |

Section 10 – STABILITY AND REACTIVITY

Stability:

Incompatibility (Materials to avoid): Hazardous Decomposition or Byproducts: Conditions to Avoid: Hazardous Polymerization: Stable None known None known Avoid high heat with flames and other sources of ignition. Will not occur



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Section 11 – TOXICOLOGICAL INFORMATION

Routes of Entry: N/A Health Hazards (Acute and Chronic): None known Carcinogenicity: No IARC Monographs: N/A Signs and Symptoms of Exposure: None known Medical Conditions generally aggravated by Exposure: None known NTP: N/A **OSHA Regulated:** No

Section 12 – ECOLOGICAL INFORMATION

 Ecotoxicity:
 Regarded as having low toxicity to aquatic organisms.

 Mobility:
 Water soluble, will partition to aqueous phase. Lost within short period through evaporation and dissolution. Poorly absorbed into soils and sediments.

 Bioaccumulation:
 Low bioaccumulation potential.

 Regardability:
 Readily biodegradable.

Section 13 – DISPOSAL CONSIDERATIONS

Appropriate Disposal / Product:

Dispose of unused product, spilled substance and waste in normal disposal container.

Section 14 – TRANSPORT INFORMATION

| Land Transport: | Not restricted. Not regulated as hazardous goods. |
|-----------------|---|
| Sea Transport: | Not restricted. Not regulated as hazardous goods. |
| Air Transport: | Not restricted. Not regulated as hazardous goods. |

Section 15 – REGULATORY INFORMATION

| Chemical Name | EC-No. | Index-No | CAS-No. | % | Classification Symbol | Labeling R-Phrases |
|--|------------|--|---------|-----------------------------|--------------------------|-----------------------|
| Ethyl Alcohol | 200-578-6 | 603-002-00-5 | 64-17-5 | 23 | None | None |
| California Propo | sition 65: | This product does not contain any substances listed on (| | California's listing of kno | own or potential | |
| Chemical Safety Assessment: Observe general laboratory safety regulations when handling chemicals. | | | | | | |

Section 16 – OTHER INFORMATION

SDS Prepared by: MMQCI Preparation Date: 23 January 2019

Disclaimer: The information contained in this SDS is provided only for use as a guide. The SDS was carefully prepared based on references and tests believed to be reliable; however, MMQCI makes no guarantee of the accuracy and completeness of the data. Any use of the data must be in accordance with applicable federal, state and local regulations.