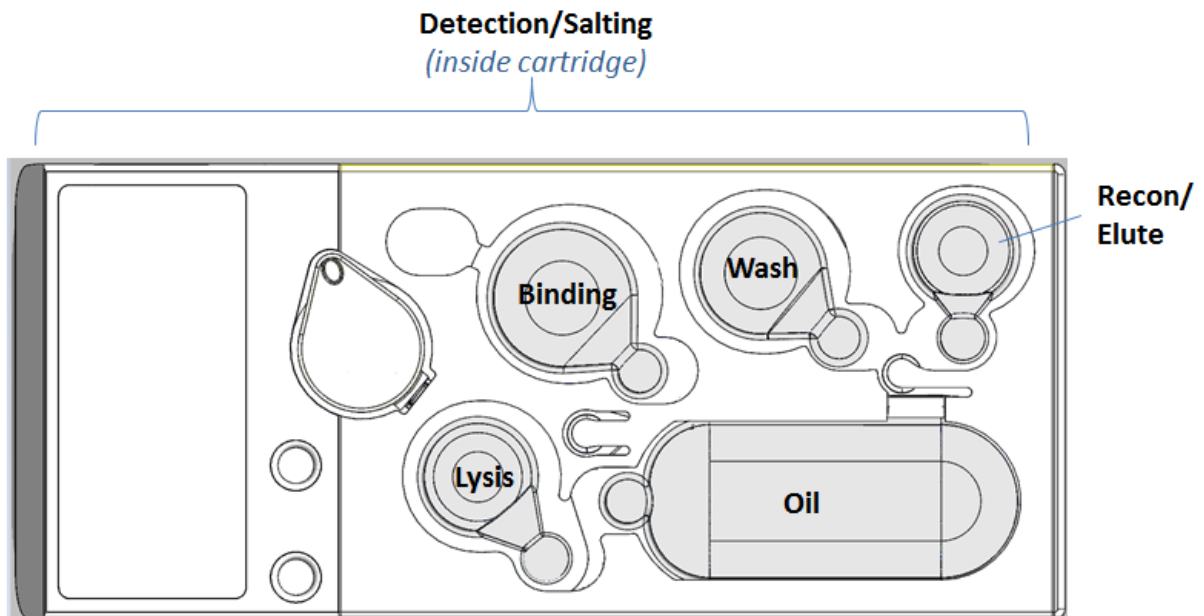


Introduction to Safety Data Sheets for ePlex[®] products

The ePlex cartridge contains six separate components for which a safety data sheet is required. The figure below shows the location and name of each component in the cartridge. When reading the Safety Data Sheet, please note the component name shown under Product Name in Section 1.



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name Detection/Salting Component for: ePlex® Blood Culture Identification Gram-Negative Panel, ePlex Blood Culture Identification Gram-Positive Panel, ePlex Fungal Pathogen Panel

Other means of identification

UN-Number UN1502

Synonyms ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Recommended use of the chemical and restrictions on use

Recommended Use In vitro diagnostic use, investigational use and for research use

Uses advised against No information available

Supplier's details

Supplier Address
GenMark Diagnostics
5964 La Place Court
Carlsbad, CA 92008
USA
TEL: 1-800-373-6767

Emergency telephone number

Emergency Telephone Number 1-800-424-9300

2. HAZARDS IDENTIFICATION


Classification

This chemical is considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Acute Oral Toxicity	Category 4
Skin Corrosion/Irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 2
Oxidizing solids	Category 1

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word	Danger	
Hazard Statements <ul style="list-style-type: none">• Harmful if swallowed• Causes skin irritation• Causes serious eye irritation• May cause fire or explosion; strong oxidizer		
		
Appearance Grayish white.	Physical State Solid (compressed).	Odor Pungent.

Precautionary Statements

Prevention

- Keep away from heat/sparks/open flames/hot surfaces - No smoking.
- Keep/Store away from clothing/ other combustible materials
- Take any precaution to avoid mixing with combustibles
- Wash face, hands and any exposed skin thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Wear protective gloves/protective clothing/eye protection/face protection.
- Wear fire/flame resistant/retardant clothing

General Advice

- Specific treatment (see supplemental instructions on the administration of antidotes on this label)

Eyes

- 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.

Skin

- Wash contaminated clothing before reuse.
- IF ON SKIN: Wash with plenty of soap and water.
- IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes
- If skin irritation occurs: Get medical advice/attention.

Ingestion

- Rinse mouth.
- IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

Fire

- In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion
- In case of fire: Use carbon dioxide, alcohol-resistant foam, or water spray for extinction.

Storage

- None

Disposal

- Dispose of contents/container to an approved waste disposal plant.

Hazard Not Otherwise Classified (HNOC)

Not applicable.

Other information

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms

ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Chemical Name	CAS-No	Weight %	Trade secret
Guanidine hydrochloride	50-01-1	45	*
Sodium perchlorate	7601-89-0	14	*

**The exact percentage (concentration) of composition has been withheld as a trade secret.*

4. FIRST AID MEASURES

Description of necessary first-aid measures

General Advice

Show this safety data sheet to the doctor in attendance. Do not get in eyes, on skin, or on clothing.

Eye Contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention if irritation persists.

Skin Contact

Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/ attention.

Inhalation

IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Consult a physician. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.

Ingestion Call a POISON CENTER or doctor/physician if exposed or you feel unwell. Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Consult a physician.

Protection of First-aiders Use personal protective equipment.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects Eye irritation/reactions. Skin irritation. Effects observed upon exposure may include the following: Nausea. Tremors. Headaches. Hypoactivity. Dizziness. Vomiting. Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Dry chemical. Alcohol-resistant foam.

Unsuitable Extinguishing Media No information available.

Specific Hazards Arising from the Chemical

Emits toxic fumes under fire conditions: Hydrogen chloride gas. Sodium oxides. Carbon oxides. Nitrogen oxides (NO_x).

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge Yes.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Use personal protective equipment. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Avoid dust formation. Avoid inhalation of dust. Refer to Section 8 for personal protective equipment.

Environmental Precautions

Environmental Precautions Prevent further leakage or spillage if safe to do so. Do not flush into surface water or sanitary sewer system. Prevent entry into waterways, sewers, basements or confined areas.

Methods and materials for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Pick up and transfer to properly labeled containers. Avoid dust formation. Do not dry sweep dust. Wipe dust with wet absorbent gauze. Keep in suitable and closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Keep away from open flames, hot surfaces and sources of ignition. Wear personal protective equipment. Do not eat, drink or smoke when using this product. Avoid dust formation. Avoid contact with skin, eyes and clothing. Remove and wash contaminated clothing before re-use.

Conditions for safe storage, including any incompatibilities

Storage Keep container tightly closed in a dry and well-ventilated place. Keep away from open flames, hot surfaces and sources of ignition. Keep away from combustible material.

Incompatible Products Organic material. Powdered metals. Strong acids. Forms shock-sensitive mixtures with other materials including powdered metals and magnesium.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection Safety glasses with side-shields. Use equipment conforming and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

Skin and Body Protection Protective gloves. Long sleeved clothing. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Respiratory Protection Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hygiene Measures When using, do not eat, drink or smoke. Provide regular cleaning of equipment, work area and clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Solid (compressed).	Appearance	Grayish white.
Odor	Pungent.	Odor Threshold	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	No data available	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known

Specific Gravity	No data available	None known
Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known

Flammable Properties Not flammable

Explosive Properties No data available
Oxidizing Properties Oxidizer.

Other information

VOC Content (%) No data available

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

Keep away from open flames, hot surfaces and sources of ignition.

Incompatible materials

Organic material. Powdered metals. Strong acids. Forms shock-sensitive mixtures with other materials including powdered metals and magnesium.

Hazardous decomposition products

May emit toxic fumes under fire conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation

May cause irritation of respiratory tract.

Eye Contact

Contact with eyes may cause serious eye irritation based on the components present within the product.

Skin Contact

Expected to be an irritant based on components

Ingestion

Harmful if swallowed.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Guanidine hydrochloride	= 475 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	-
Sodium perchlorate	= 2100 mg/kg (Rat)	-	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization Did not cause sensitization on laboratory animals.
Mutagenic Effects In vitro tests did not show mutagenic effects.
Carcinogenicity Contains no ingredients above reportable quantities listed as a carcinogen.

Reproductive Toxicity No information available.
STOT - single exposure No information available.
STOT - repeated exposure No information available.
Chronic Toxicity Avoid repeated exposure.
Target Organ Effects Liver. Eyes. Skin. Blood. Gastrointestinal tract (GI).
Aspiration Hazard No information available.

Numerical measures of toxicity - Product

Unknown acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral 847 mg/kg, Acute toxicity estimate

12. ECOLOGICAL INFORMATION

Ecotoxicity

This product does not contain any substances known to be hazardous to the environment.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Guanidine hydrochloride 50-01-1		LC50 48 h: = 1758 mg/L (Leuciscus idus)	EC50 = 88.7 mg/L 18 h	

Persistence and Degradability No information available.

Bioaccumulation No information available.

Chemical Name	Log Pow
Guanidine hydrochloride	-1.7

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods Dispose of contents/container in accordance with local regulation

Contaminated Packaging Do not re-use empty containers.

US EPA Waste Number D001

14. TRANSPORT INFORMATION

Note: When sold in quantities of less than or equal to 1 ml or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the requirements of the De Minimis Quantities exemption, per IATA 2.6.10, IMDG 3.5.1.3, ADR 3.5.1.4 and DOT 49 CFR 173.4b. Therefore, this product is not subject to dangerous goods regulations.

Quantity of sodium perchlorate per inner packaging:
0.03 g in 12 test
0.12 g in 48 test

DOT

UN-Number UN1502
Proper shipping name Sodium perchlorate
Hazard Class 5.1
Packing Group II
Description UN1502, Sodium perchlorate, 5.1, II
Emergency Response Guide Number 140

TDG

UN-Number UN1502
Proper Shipping Name Sodium perchlorate
Hazard Class 5.1
Packing Group II
Description UN1502, Sodium perchlorate, 5.1, II

MEX

UN-Number UN1502
Proper Shipping Name Sodium perchlorate
Hazard Class 5.1
Packing Group II
Description UN1502, Sodium perchlorate, 5.1, II

ICAO

UN-Number UN1502
Proper shipping name Sodium perchlorate
Hazard Class 5.1
Packing Group II
Description UN1502, Sodium perchlorate, 5.1, II

IATA

UN-Number UN1502
Proper Shipping Name Sodium perchlorate
Hazard Class 5.1
Packing Group II
ERG Code 5L
Description UN1502, Sodium perchlorate, 5.1, II

IMDG/IMO

UN-Number UN1502
Proper Shipping Name Sodium perchlorate
Hazard Class 5.1
Packing Group II
EmS No. F-H, S-Q
Description UN1502, Sodium perchlorate, 5.1, II

RID

UN-Number UN1502
Proper Shipping Name Sodium perchlorate
Hazard Class 5.1
Packing Group II
Classification Code O2
Description UN1502, Sodium perchlorate, 5.1, II

ADR

UN-Number UN1502
Proper Shipping Name Sodium perchlorate
Hazard Class 5.1
Packing Group II

Classification Code O2
Tunnel Restriction Code (E)
Description UN1502, Sodium perchlorate, 5.1, II, (E)

ADN

Proper Shipping Name Sodium perchlorate
Hazard Class 5.1
Packing Group II
Classification Code O2
Description UN1502, Sodium perchlorate, 5.1, II
Limited Quantity 1 kg

15. REGULATORY INFORMATION

International Inventories

TSCA All components of this product are either listed or are exempt on the TSCA inventory.
DSL Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard Yes
Chronic Health Hazard No
Fire Hazard Yes
Sudden Release of Pressure Hazard No
Reactive Hazard No

Clean Water Act

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

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Sodium perchlorate	X	X	X		X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

NFPA	Health Hazard 2	Flammability 0	Instability 2	Physical and Chemical Hazards OX
HMIS	Health Hazard 2	Flammability 0	Physical Hazard 2	Personal Protection D

Prepared By Product Stewardship
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

Issuing Date 11-Apr-2017
Revision Date 11-Apr-2017
Revision Note Initial Release.

General Disclaimer

The information provided herein is correct to the best of our knowledge, information and belief at the date of its publication. The information provided is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. We make no warranty, express or implied, with respect to such information and we assume no liability as a result of its use. Users should make their own investigation to determine the suitability of this information for their particular purposes and must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. GenMark Diagnostics, Inc. shall not be held liable for any damage or losses resulting from the handling, use, storage or disposal of or contact with this product.

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End of Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name Binding Component for: ePlex[®] Blood Culture Identification Gram-Negative Panel, ePlex Blood Culture Identification Gram-Positive Panel, ePlex Fungal Pathogen Panel

Other means of identification

Synonyms ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Recommended use of the chemical and restrictions on use

Recommended Use In vitro diagnostic use, investigational use and for research use

Uses advised against No information available

Supplier's details

Supplier Address
GenMark Diagnostics
5964 La Place Court
Carlsbad, CA 92008
USA
TEL: 1-800-373-6767

Emergency telephone number

Emergency Telephone Number 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word	None	
The product contains no substances which at their given concentration are considered to be hazardous to health		
Appearance Colorless.	Physical State Liquid.	Odor No information available.

Precautionary Statements

Prevention

- None

General Advice

- None

Storage

- None

Disposal

- None

Hazard Not Otherwise Classified (HNOC)

Not applicable.

Other information

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Synonyms

ePlex Blood Culture Identification Gram-Negative Panel,
EA002012, EA002112, EA002212, EA002048, EA002148,
EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel,
EA003012, EA003112, EA003212, EA003048, EA003148,
EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112,
EA004212, EA004048, EA004148, EA004248, EA005012,
EA005048, EA005112, EA005148, EA005212, EA005248,
KT022093, KT022094, KT022095, KT022277, KT022278,
KT022279

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Skin Contact	Wash skin with soap and water. If skin irritation or rash occurs: Get medical advice/attention.
Inhalation	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Consult a physician.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects None known

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Dry chemical. Alcohol-resistant foam.

Unsuitable Extinguishing Media No information available.

Specific Hazards Arising from the Chemical

Emits toxic fumes under fire conditions: Hydrogen chloride gas, Carbon oxides, Nitrogen oxides (NO_x), Sodium oxides.

Explosion Data

Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Use personal protective equipment as required. Refer to Section 8 for personal protective equipment.

Environmental Precautions

Environmental Precautions See Section 12 for additional Ecological Information.

Methods and materials for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Keep in suitable and closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Wash thoroughly after handling. Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products Strong oxidizing agents.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Measures Showers
 Eyewash stations
 Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection Safety glasses with side-shields. Use equipment conforming and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

Skin and Body Protection Protective gloves. Lightweight protective clothing. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Respiratory Protection Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid.	Appearance	Colorless.
Odor	No information available.	Odor Threshold	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	No data available	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Specific Gravity	No data available	None known
Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known

Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known
Flammable Properties	Not flammable	
Explosive Properties	No data available	
Oxidizing Properties	No data available	
<u>Other information</u>		
VOC Content (%)	No data available	

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known based on information supplied.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

May emit toxic fumes under fire conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	Product does not present an acute toxicity hazard based on known or supplied information.
Inhalation	There is no data available for this product.
Eye Contact	There is no data available for this product.
Skin Contact	There is no data available for this product.
Ingestion	There is no data available for this product.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms None known

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization No information available.
Mutagenic Effects No information available.
Carcinogenicity Contains no ingredients above reportable quantities listed as a carcinogen.

Reproductive Toxicity No information available.
STOT - single exposure No information available.
STOT - repeated exposure No information available.
Aspiration Hazard No information available.

Numerical measures of toxicity - Product

Unknown acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral >5000 mg/kg
LD50 Dermal >5000 mg/kg
dust/mist >5 mg/L

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Polyethylene glycol 25322-68-3		LC50 24 h: > 5000 mg/L (Carassius auratus)	EC50 = 100000 mg/L 15 min	

Persistence and Degradability No information available.

Bioaccumulation No information available.

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Complies
DSL Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

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

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

<u>NFPA</u>	Health Hazard 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
<u>HMIS</u>	Health Hazard 1	Flammability 0	Physical Hazard 0	Personal Protection X

Prepared By Product Stewardship
 23 British American Blvd.
 Latham, NY 12110
 1-800-572-6501

Issuing Date 11-Apr-2017
Revision Date 11-Apr-2017
Revision Note Initial Release.

General Disclaimer

The information provided herein is correct to the best of our knowledge, information and belief at the date of its publication. The information provided is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. We make no warranty, express or implied, with respect to such information and we assume no liability as a result of its use. Users should make their own investigation to determine the suitability of this information for their particular purposes and must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. GenMark Diagnostics, Inc. shall not be held liable for any damage or losses resulting from the handling, use, storage or disposal of or contact with this product.

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End of Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name Lysis Component for: ePlex[®] Blood Culture Identification Gram-Negative Panel, ePlex Blood Culture Identification Gram-Positive Panel, ePlex Fungal Pathogen Panel

Other means of identification

Synonyms ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Recommended use of the chemical and restrictions on use

Recommended Use In vitro diagnostic use, investigational use and for research use

Uses advised against No information available

Supplier's details

Supplier Address
GenMark Diagnostics
5964 La Place Court
Carlsbad, CA 92008
USA
TEL: 1-800-373-6767

Emergency telephone number

Emergency Telephone Number 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification


This chemical is considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Acute Oral Toxicity	Category 4
Skin Corrosion/Irritation	Category 2

Serious Eye Damage/Eye Irritation	Category 2
-----------------------------------	------------

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word	Warning	
Hazard Statements <ul style="list-style-type: none">• Harmful if swallowed• Causes skin irritation• Causes serious eye irritation		
		
Appearance Colorless.	Physical State Liquid.	Odor No information available.

Precautionary Statements

Prevention

- Wash face, hands and any exposed skin thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Wear protective gloves/protective clothing/eye protection/face protection.

General Advice

- Specific treatment (see supplemental instructions on the administration of antidotes on this label)

Eyes

- 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.

Skin

- IF ON SKIN: Wash with plenty of soap and water.
- If skin irritation occurs: Get medical advice/attention.
- Take off contaminated clothing and wash before reuse.

Ingestion

- IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
- Rinse mouth.

Storage

- None

Disposal

- Dispose of contents/container to an approved waste disposal plant.

Hazard Not Otherwise Classified (HNOC)

Not applicable.

Other information

Harmful to aquatic life.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms

ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Chemical Name	CAS-No	Weight %	Trade secret
Urea	57-13-6	25-50	*
Guanidine hydrochloride	50-01-1	25-50	*
Sodium lauryl sulfate	151-21-3	<2	*

**The exact percentage (concentration) of composition has been withheld as a trade secret.*

4. FIRST AID MEASURES

Description of necessary first-aid measures

General Advice

Show this safety data sheet to the doctor in attendance. Do not get in eyes, on skin, or on clothing.

Eye Contact

Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention if irritation persists.

Skin Contact

Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/ attention.

Inhalation

IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Consult a physician. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.

Ingestion

Call a POISON CENTER or doctor/physician if exposed or you feel unwell. Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Consult a physician.

Protection of First-aiders

Use personal protective equipment.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects

Eye irritation/reactions. Skin irritation. Effects observed upon exposure may include the following: Nausea. Tremors. Headaches. Hypoactivity. Dizziness. Vomiting. Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Dry chemical. Alcohol-resistant foam.

Unsuitable Extinguishing Media No information available.

Specific Hazards Arising from the Chemical

Emits toxic fumes under fire conditions: Hydrogen chloride gas. Sodium oxides. Carbon oxides. Nitrogen oxides (NO_x).

Explosion Data

Sensitivity to Mechanical Impact

None.

Sensitivity to Static Discharge

None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions

Use personal protective equipment. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Refer to Section 8 for personal protective equipment.

Environmental Precautions

Environmental Precautions

Prevent further leakage or spillage if safe to do so. Avoid release to the environment. Do not flush into surface water or sanitary sewer system. Prevent entry into waterways, sewers, basements or confined areas. See Section 12 for additional Ecological Information.

Methods and materials for containment and cleaning up

Methods for Containment

Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up

Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Keep in suitable and closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not breathe vapors or spray mist. Remove and wash contaminated clothing before re-use. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage

Keep container tightly closed in a dry and well-ventilated place.

Incompatible Products

Strong oxidizing agents.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines

This product does not contain any hazardous materials with occupational exposure limits

established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Measures Showers
 Eyewash stations
 Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection Safety glasses with side-shields. Use equipment conforming and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

Skin and Body Protection Protective gloves. Long sleeved clothing. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Respiratory Protection Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hygiene Measures When using, do not eat, drink or smoke. Provide regular cleaning of equipment, work area and clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid.	Appearance	Colorless.
Odor	No information available.	Odor Threshold	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	No data available	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Specific Gravity	No data available	None known
Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known
 Flammable Properties	 Not flammable	
 Explosive Properties	 No data available	
Oxidizing Properties	No data available	

Other information

VOC Content (%) No data available

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known based on information supplied.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

May emit toxic fumes under fire conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation

May cause irritation of respiratory tract.

Eye Contact

Contact with eyes may cause serious eye irritation based on the components present within the product.

Skin Contact

Expected to be an irritant based on components

Ingestion

Harmful if swallowed.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Guanidine hydrochloride	= 475 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	-
Urea	= 8471 mg/kg (Rat)	-	-
Sodium lauryl sulfate	= 1288 mg/kg (Rat)	= 200 mg/kg (Rabbit)	>3900 mg/m ³ (Rat) 1 h

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization

Did not cause sensitization on laboratory animals.

Mutagenic Effects

In vitro tests did not show mutagenic effects.

Carcinogenicity

Contains no ingredients above reportable quantities listed as a carcinogen.

Reproductive Toxicity STOT - single exposure

No information available.
No information available.

STOT - repeated exposure No information available.
Chronic Toxicity Avoid repeated exposure.
Target Organ Effects Liver. Eyes. Skin. Blood. Gastrointestinal tract (GI).
Aspiration Hazard No information available.

Numerical measures of toxicity - Product

Unknown acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral 484 mg/kg; Acute toxicity estimate
LD50 Dermal 28601 mg/kg; Acute toxicity estimate mg/L

12. ECOLOGICAL INFORMATION

Ecotoxicity

Harmful to aquatic life

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Guanidine hydrochloride 50-01-1		LC50 48 h: = 1758 mg/L (Leuciscus idus)	EC50 = 88.7 mg/L 18 h	
Urea 57-13-6		LC50: 16200-18300 mg/L Poecilia reticulata 96 h	EC50 = 23914 mg/L 5 min	EC50 48 h: = 3910 mg/L Static (Daphnia magna) EC50 24 h: > 10000 mg/L (Daphnia magna Straus)
Sodium lauryl sulfate 151-21-3	EC50 72 h: = 53 mg/L (Desmodesmus subspicatus) EC50 96 h: 30 - 100 mg/L (Desmodesmus subspicatus) EC50 96 h: = 117 mg/L (Pseudokirchneriella subcapitata) EC50 96 h: 3.59 - 15.6 mg/L static (Pseudokirchneriella subcapitata) EC50 96 h: = 42 mg/L (Desmodesmus subspicatus)	LC50 96 h: 8 - 12.5 mg/L static (Pimephales promelas) LC50 96 h: 15 - 18.9 mg/L static (Pimephales promelas) LC50 96 h: 22.1 - 22.8 mg/L static (Pimephales promelas) LC50 96 h: 4.3 - 8.5 mg/L static (Oncorhynchus mykiss) LC50 96 h: = 4.62 mg/L flow-through (Oncorhynchus mykiss) LC50 96 h: = 4.2 mg/L (Oncorhynchus mykiss) LC50 96 h: 10.2 - 22.5 mg/L semi-static (Pimephales promelas) LC50 96 h: 6.2 - 9.6 mg/L (Pimephales promelas) LC50 96 h: 13.5 - 18.3 mg/L semi-static (Poecilia reticulata) LC50 96 h: 10.8 - 16.6 mg/L static (Poecilia reticulata) LC50 96 h: = 1.31 mg/L semi-static (Cyprinus carpio) LC50 96 h: = 7.97 mg/L flow-through (Brachydanio rerio) LC50 96 h: 9.9 - 20.1 mg/L semi-static (Brachydanio rerio) LC50 96 h: 4.06 - 5.75 mg/L static (Lepomis macrochirus) LC50 96 h: 4.2 - 4.8 mg/L flow-through (Lepomis macrochirus) LC50 96 h: = 4.5 mg/L (Lepomis macrochirus) LC50 96 h: 5.8 - 7.5 mg/L static (Pimephales promelas) LC50 48 h: = 4.1 mg/L static (Leuciscus idus)	EC50 = 0.46 mg/L 30 min EC50 = 0.72 mg/L 15 min EC50 = 1.19 mg/L 5 min	EC50 48 h: = 1.8 mg/L (Daphnia magna) EC50 24 h: = 21.2 mg/L (Daphnia magna)

Persistence and Degradability No information available.

Bioaccumulation No information available.

Chemical Name	Log Pow
Urea	-1.59
Guanidine hydrochloride	-1.7
Sodium lauryl sulfate	1.6

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA All components of this product are either listed or are exempt on the TSCA inventory.
DSL Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

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

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION				
NFPA	Health Hazard 2	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazard 2	Flammability 0	Physical Hazard 0	Personal Protection X
Prepared By	Product Stewardship 23 British American Blvd. Latham, NY 12110 1-800-572-6501			
Issuing Date	11-Apr-2017			
Revision Date	11-Apr-2017			
Revision Note	Initial Release.			

General Disclaimer

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End of Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name Oil Component for: ePlex[®] Blood Culture Identification Gram-Negative Panel, ePlex Blood Culture Identification Gram-Positive Panel, ePlex Fungal Pathogen Panel

Other means of identification

Synonyms

ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Recommended use of the chemical and restrictions on use

Recommended Use In vitro diagnostic use, investigational use and for research use

Uses advised against No information available

Supplier's details

Supplier Address

GenMark Diagnostics
5964 La Place Court
Carlsbad, CA 92008
USA
TEL: 1-800-373-6767

Emergency telephone number

Emergency Telephone Number 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word	None		
The product contains no substances which at their given concentration are considered to be hazardous to health			
Appearance	Clear. Viscous.	Physical State	Liquid.
		Odor	No information available.

Precautionary Statements

Prevention

- None

General Advice

- None

Storage

- None

Disposal

- None

Hazard Not Otherwise Classified (HNOC)

Not applicable.

Other information

None known.

100% of the mixture consists of ingredient(s) of unknown toxicity.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms

ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Chemical Name	CAS-No	Weight %	Trade secret
Poly[oxy(dimethylsilylene)]	9016-00-6	>95	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Skin Contact	Wash skin with soap and water. If skin irritation or rash occurs: Get medical advice/attention.
Inhalation	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Consult a physician.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects None known

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Dry chemical. Alcohol-resistant foam.

Unsuitable Extinguishing Media No information available.

Specific Hazards Arising from the Chemical

Thermal decomposition can lead to release of irritating and toxic gases and vapors.

Explosion Data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Use personal protective equipment as required. Refer to Section 8 for personal protective equipment.

Environmental Precautions

Environmental Precautions See Section 12 for additional Ecological Information.

Methods and materials for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Keep in suitable and closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Wash thoroughly after handling. Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products Oxidizing agents.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Measures Showers
 Eyewash stations
 Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection Tightly fitting safety goggles. Use equipment conforming and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

Skin and Body Protection Lightweight protective clothing. Nitrile rubber. Neoprene gloves. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Respiratory Protection Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hygiene Measures Do not eat, drink or smoke when using this product. Keep away from food, drink and animal feeding stuffs. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Provide regular cleaning of equipment, work area and clothing. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid.	Appearance	Clear. Viscous.
Odor	No information available.	Odor Threshold	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	No data available	None known
Melting Point/Range	< -40 °C	None known
Boiling Point/Boiling Range	> 205 °C	None known
Flash Point	135 °C	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known

Specific Gravity	0.918	None known
Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	443 °C	None known
Decomposition Temperature	No data available	None known
Viscosity	5 cSt	None known

Flammable Properties Not flammable

Explosive Properties No data available
Oxidizing Properties No data available

Other information

VOC Content (%) No data available

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

Heat, flames and sparks.

Incompatible materials

Oxidizing agents.

Hazardous decomposition products

Formaldehyde. Silicon dioxide. Organic acids.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	Product does not present an acute toxicity hazard based on known or supplied information.
Inhalation	No known hazard by inhalation. Inhalation of mist may cause irritation to the respiratory system.
Eye Contact	May cause slight irritation.
Skin Contact	May cause mild skin irritation.
Ingestion	No known effect. Ingestion may cause stomach discomfort.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
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Poly[oxy(dimethylsilylene)]	> 40000 mg/kg (rat)	-	>535 mg/L (rat)
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Symptoms related to the physical, chemical and toxicological characteristics

Symptoms None known

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization Not classified
Mutagenic Effects Based on available data, the classification criteria are not met.
Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive Toxicity Based on available data, the classification criteria are not met.
Developmental Toxicity Based on available data, the classification criteria are not met.
STOT - single exposure Based on available data, the classification criteria are not met
STOT - repeated exposure Based on available data, the classification criteria are not met
Chronic Toxicity Contains a known or suspected reproductive toxin.
Aspiration Hazard None of the ingredients are known to be an aspiration hazard.

Numerical measures of toxicity - Product

Unknown acute toxicity 100% of the mixture consists of ingredient(s) of unknown toxicity.
The following values are calculated based on chapter 3.1 of the GHS document:
LD50 Oral >2000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Poly[oxy(dimethylsilylene)] 9016-00-6		LC50 96 h: > 10000 mg/L static (Lepomis macrochirus) LC50 96 h: > 10000 mg/L static (Oncorhynchus mykiss)		

Persistence and Degradability No information available.

Bioaccumulation No information available.

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA All components of this product are either listed or are exempt on the TSCA inventory.
DSL Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

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

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

<u>NFPA</u>	Health Hazard 1	Flammability 1	Instability 0	Physical and Chemical Hazards -
<u>HMIS</u>	Health Hazard 1	Flammability 1	Physical Hazard 0	Personal Protection X

Prepared By Product Stewardship
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Issuing Date 11-Apr-2017
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End of Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name

Recon/Elution Component for: ePlex[®] Blood Culture Identification Gram-Negative Panel, ePlex Blood Culture Identification Gram-Positive Panel, ePlex Fungal Pathogen Panel

Other means of identification

Synonyms

ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Recommended use of the chemical and restrictions on use

Recommended Use

In vitro diagnostic use, investigational use and for research use

Uses advised against

No information available

Supplier's details

Supplier Address

GenMark Diagnostics
5964 La Place Court
Carlsbad, CA 92008
USA
TEL: 1-800-373-6767

Emergency telephone number

Emergency Telephone Number

1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word	None		
The product contains no substances which at their given concentration are considered to be hazardous to health			
Appearance	Colorless.	Physical State	Liquid.
		Odor	No information available.

Precautionary Statements

Prevention

- None

General Advice

- None

Storage

- None

Disposal

- None

Hazard Not Otherwise Classified (HNOC)

Not applicable.

Other information

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms

ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Chemical Name	CAS-No	Weight %	Trade secret
Sodium azide	26628-22-8	0.2	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Skin Contact	Wash skin with soap and water. If skin irritation or rash occurs: Get medical advice/attention.
Inhalation	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Consult a physician.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects None known

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Dry chemical. Alcohol-resistant foam.

Unsuitable Extinguishing Media No information available.

Specific Hazards Arising from the Chemical

Emits toxic fumes under fire conditions: Hydrogen chloride gas, Carbon oxides, Nitrogen oxides (NO_x), Sodium oxides.

Explosion Data

Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Use personal protective equipment as required. Refer to Section 8 for personal protective equipment.

Environmental Precautions

Environmental Precautions See Section 12 for additional Ecological Information.

Methods and materials for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Keep in suitable and closed containers for disposal. Sodium azide has been reported to form lead or copper azides in laboratory plumbing. These azides are potentially explosive. To prevent buildup, flush plumbing with a large volume of water while disposing of these

solutions in the sink.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Wash thoroughly after handling. Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products Strong oxidizing agents.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sodium azide 26628-22-8	Ceiling: 0.29 mg/m ³ NaN ₃ Ceiling: 0.11 ppm Hydrazoic acid vapor	(vacated) S* (vacated) Ceiling: 0.1 ppm HN ₃ (vacated) Ceiling: 0.3 mg/m ³ NaN ₃	Ceiling: 0.1 ppm HN ₃ Ceiling: 0.3 mg/m ³ NaN ₃

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection Safety glasses with side-shields. Use equipment conforming and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

Skin and Body Protection Protective gloves. Lightweight protective clothing. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Respiratory Protection Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid.	Appearance	Colorless.
Odor	No information available.	Odor Threshold	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	No data available	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known

Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Specific Gravity	No data available	None known
Water Solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known
Flammable Properties	Not flammable	
Explosive Properties	No data available	
Oxidizing Properties	No data available	
<u>Other information</u>		
VOC Content (%)	No data available	

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

If sodium azide is eliminated through metal piping and dries, in adequate quantity, it could react with lead and copper metals forming explosive metal salts. If these products are disposed through the drain, flush with plenty of water to prevent explosive metal salt build-up. Follow local regulations for disposal of this product.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

May emit toxic fumes under fire conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	There is no data available for this product
Inhalation	There is no data available for this product.

Eye Contact There is no data available for this product.
Skin Contact There is no data available for this product.
Ingestion There is no data available for this product.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium azide	= 27 mg/kg (Rat)	= 20 mg/kg (Rabbit) = 50 mg/kg (Rat)	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms None known

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization No information available.
Mutagenic Effects No information available.
Carcinogenicity Contains no ingredients above reportable quantities listed as a carcinogen.

Reproductive Toxicity No information available.
STOT - single exposure No information available.
STOT - repeated exposure No information available.
Aspiration Hazard No information available.

Numerical measures of toxicity - Product

Unknown acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral >5000 mg/kg
LD50 Dermal >5000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated. Contains a substance which is very toxic to the aquatic environment with long lasting effects at very low concentrations.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Sodium azide 26628-22-8		LC50 96 h: = 0.7 mg/L (Lepomis macrochirus) LC50 96 h: = 0.8 mg/L (Oncorhynchus mykiss) LC50 96 h: = 5.46 mg/L flow-through (Pimephales promelas)		

Persistence and Degradability No information available.

Bioaccumulation No information available.

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local

regulations for additional requirements.

Contaminated Packaging Do not re-use empty containers.

Component	RCRA - Halogenated Organic Compounds	RCRA - P Series Wastes	RCRA - F Series Wastes	RCRA - K Series Wastes
Sodium azide 26628-22-8 (0.2)		P105		

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Complies
DSL Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

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

CERCLA

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Sodium azide	1000 lb	1000 lb	RQ 1000 lb final RQ RQ 454 kg final RQ

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Sodium azide	X	X	X		X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

NFPA Health Hazard 1 Flammability 0 Instability 0 Physical and Chemical Hazards -

HMIS Health Hazard 1 Flammability 0 Physical Hazard 0 Personal Protection X

Prepared By Product Stewardship
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Issuing Date 11-Apr-2017
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Revision Note Initial Release.

General Disclaimer

The information provided herein is correct to the best of our knowledge, information and belief at the date of its publication. The information provided is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. We make no warranty, express or implied, with respect to such information and we assume no liability as a result of its use. Users should make their own investigation to determine the suitability of this information for their particular purposes and must make their own determination of the effects, properties, protections and disposal which pertain to their particular conditions. GenMark Diagnostics, Inc. shall not be held liable for any damage or losses resulting from the handling, use, storage or disposal of or contact with this product.

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End of Safety Data Sheet

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name Wash Component for: ePlex[®] Blood Culture Identification Gram-Negative Panel, ePlex Blood Culture Identification Gram-Positive Panel, ePlex Fungal Pathogen Panel

Other means of identification

Synonyms

ePlex Blood Culture Identification Gram-Negative Panel, EA002012, EA002112, EA002212, EA002048, EA002148, EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel, EA003012, EA003112, EA003212, EA003048, EA003148, EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112, EA004212, EA004048, EA004148, EA004248, EA005012, EA005048, EA005112, EA005148, EA005212, EA005248, KT022093, KT022094, KT022095, KT022277, KT022278, KT022279

Recommended use of the chemical and restrictions on use

Recommended Use In vitro diagnostic use, investigational use and for research use

Uses advised against No information available

Supplier's details

Supplier Address
GenMark Diagnostics
5964 La Place Court
Carlsbad, CA 92008
USA
TEL: 1-800-373-6767

Emergency telephone number

Emergency Telephone Number 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word	None	
The product contains no substances which at their given concentration are considered to be hazardous to health		
Appearance Colorless.	Physical State Liquid.	Odor No information available.

Precautionary Statements

Prevention

- None

General Advice

- None

Storage

- None

Disposal

- None

Hazard Not Otherwise Classified (HNOC)

Not applicable.

Other information

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Synonyms

ePlex Blood Culture Identification Gram-Negative Panel,
EA002012, EA002112, EA002212, EA002048, EA002148,
EA002248, KT021836, KT022078, KT022079

ePlex Blood Culture Identification Gram-Positive Panel,
EA003012, EA003112, EA003212, EA003048, EA003148,
EA003248, KT021791, KT022080, KT022081

ePlex Fungal Pathogen Panel, EA004012, EA004112,
EA004212, EA004048, EA004148, EA004248, EA005012,
EA005048, EA005112, EA005148, EA005212, EA005248,
KT022093, KT022094, KT022095, KT022277, KT022278,
KT022279

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Skin Contact	Wash skin with soap and water. If skin irritation or rash occurs: Get medical advice/attention.
Inhalation	IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur. If breathing is difficult, give oxygen. If not breathing, give artificial respiration.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Consult a physician.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects None known

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Dry chemical. Alcohol-resistant foam.

Unsuitable Extinguishing Media No information available.

Specific Hazards Arising from the Chemical

Emits toxic fumes under fire conditions: Hydrogen chloride gas, Carbon oxides, Nitrogen oxides (NOx), Sodium oxides.

Explosion Data

Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Use personal protective equipment as required. Refer to Section 8 for personal protective equipment.

Environmental Precautions

Environmental Precautions See Section 12 for additional Ecological Information.

Methods and materials for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Keep in suitable and closed containers for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Avoid breathing vapors or mists. Wash thoroughly after handling. Use personal protective equipment as required.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products Strong oxidizing agents.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Measures Showers
 Eyewash stations
 Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection Safety glasses with side-shields. Use equipment conforming and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

Skin and Body Protection Protective gloves. Lightweight protective clothing. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Respiratory Protection Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid.	Appearance	Colorless.
Odor	No information available.	Odor Threshold	No information available.

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	No data available	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	No data available	None known
Flash Point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Specific Gravity	No data available	None known
Water Solubility	No data available	None known

Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known

Flammable Properties Not flammable

Explosive Properties No data available

Oxidizing Properties No data available

Other information

VOC Content (%) No data available

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known based on information supplied.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

May emit toxic fumes under fire conditions.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation

Eye Contact

Skin Contact

Ingestion

Product does not present an acute toxicity hazard based on known or supplied information.

There is no data available for this product.

There is no data available for this product.

There is no data available for this product.

There is no data available for this product.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms None known

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization No information available.
Mutagenic Effects No information available.
Carcinogenicity Contains no ingredients above reportable quantities listed as a carcinogen.

Reproductive Toxicity No information available.
STOT - single exposure No information available.
STOT - repeated exposure No information available.
Aspiration Hazard No information available.

Numerical measures of toxicity - Product

Unknown acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral >5000 mg/kg
LD50 Dermal >5000 mg/kg
Inhalation
dust/mist >5 mg/L

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Persistence and Degradability No information available.

Bioaccumulation No information available.

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG/IMO Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Complies
DSL Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

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

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

<u>NFPA</u>	Health Hazard 1	Flammability 0	Instability 0	Physical and Chemical Hazards -
<u>HMIS</u>	Health Hazard 1	Flammability 0	Physical Hazard 0	Personal Protection X

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End of Safety Data Sheet