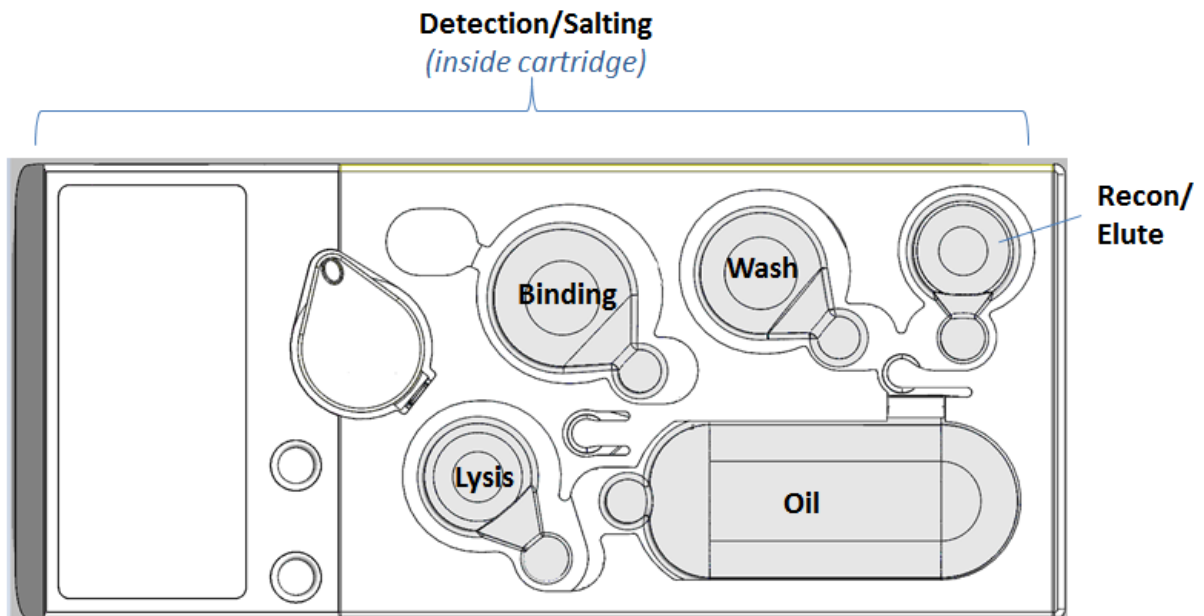


Introduction to Safety Data Sheets for ePlex[®] products

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.



Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. 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

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

Contains Guanidine hydrochloride; Sodium perchlorate

1.2. Relevant identified uses of the substance or mixture and uses advised against

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

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Importer	Supplier
GenMark Diagnostics Europe GmbH	GenMark Diagnostics
Chollerstrasse 4	5964 La Place Court
6300 Zug	Carlsbad, CA 92008
Switzerland	USA
TEL: +41 41 530 6526	TEL: 1-800-373-6767

For further information, please contact

E-mail address info@genmarkdx.com

1.4. Emergency telephone number

Emergency Telephone Number 1-800-424-9300
+1 703-527-3887 (Collect calls accepted)

Europe	112
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Section 2. Hazards identification

2.1. - Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Acute oral toxicity	Category 4
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Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2

Physical hazards

Oxidizing solids	Category 1
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2.2. Label elements



Signal Word

Danger

Hazard statements

- H302 - Harmful if swallowed
- H315 - Causes skin irritation
- H319 - Causes serious eye irritation
- H271 - May cause fire or explosion; strong oxidiser

Precautionary statements

- P210 - Keep away from heat
- P220 - Keep/Store away from clothing/ combustible materials
- P221 - Take any precaution to avoid mixing with combustibles
- P280 - Wear protective gloves/ eye protection/ face protection
- P371 + P380 + P375 - In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion
- P370 + P378 - In case of fire: Use carbon dioxide, alcohol-resistant foam, or water spray for extinction

2.3. Other information

None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Chemical Name	EC-No	CAS-No	Weight percent	EU - GHS Substance Classification	REACH No.
Guanidine hydrochloride	200-002-3	50-01-1	30-60	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	no data available

Sodium perchlorate	231-511-9	7601-89-0	10-30	Acute Tox. 4 (H302) Ox. Sol. 1 (H271)	no data available
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For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1. Description of first aid measures

General advice	Do not get in eyes, on skin, or on clothing. Show this safety data sheet to the doctor in attendance.
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.
Ingestion	Call a POISON CENTRE 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.
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.
Protection of first-aiders	Use personal protective equipment.

4.2. Most important symptoms and effects, both acute and delayed

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

Notes to physician	Treat symptomatically.
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Section 5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media

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

Extinguishing Media Which Must not be Used for Safety Reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards Arising from the Substance or Preparation Itself, Combustion Products, Resulting Gases

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

5.3. Advice for firefighters

Special protective equipment for fire-fighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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.

6.2. Environmental precautions

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

6.3. Methods and materials for containment and cleaning up

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

6.4. Reference to other sections

See Section 12 for additional information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handling

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

Hygiene measures

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

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end uses

Exposure scenario

No information available

Other Guidelines

No information available

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits

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

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering measures	Ensure adequate ventilation, especially in confined areas.
Personal protective equipment	Personal protection equipment should be chosen according to the GEN standards
Eye 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	Long sleeved clothing.
Hand protection	Protective 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 GEN (EU).

Environmental Exposure Controls Do not allow material to contaminate ground water system.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State	Solid (compressed)	Appearance	Grayish white
Odour	pungent		

Property	Values	Remarks/ - Method
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	no data available	None known
Vapour pressure	no data available	None known
Vapour density	no data available	None known
Relative density	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
Decomposition temperature	no data available	None known
Viscosity	no data available	None known

Explosive properties No information available
Oxidising properties oxidiser.

9.2. Other information

VOC Content (%) No information available

Section 10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

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

Incompatible materials

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

10.6. Hazardous decomposition products

May emit toxic fumes under fire conditions.

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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)		

Sensitisation

Did not cause sensitisation on laboratory animals.

Mutagenic effects

In vitro tests did not show mutagenic effects.

Carcinogenic effects

Contains no ingredient listed as a carcinogen.

Reproductive toxicity

No information available.

Developmental Toxicity

No information available.

Specific target organ systemic toxicity (single exposure)

No information available.

Specific target organ systemic toxicity (repeated exposure)

No information available.

Target Organ Effects

Skin. Eyes. Gastrointestinal tract (GI). Liver. Blood.

Aspiration hazard No information available.

Section 12. Ecological information

12.1. Toxicity

Ecotoxicity effects

Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia magna (Water flea)
Guanidine hydrochloride		LC50 48 h: = 1758 mg/L (Leuciscus idus)	EC50 = 88.7 mg/L 18 h	

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

Chemical Name	log Pow
Guanidine hydrochloride	-1.7

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors

Section 13. Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Other Information According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

Section 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

IMDG/IMO

14.1. UN-Number	UN1502
14.2. Proper shipping name	Sodium perchlorate
14.3. Hazard class	5.1
14.4. Packing group	II
Description	UN1502, Sodium perchlorate, 5.1, II
14.5. Marine pollutant	None
14.6. Special Provisions	none
EmS	F-H, S-Q
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

RID

14.1. UN-Number	UN1502
14.2. Proper shipping name	Sodium perchlorate
14.3. Hazard class	5.1
14.4. Packing group	II
Description	UN1502, Sodium perchlorate, 5.1, II
14.5. Environmental hazard.	None
14.6. Special Provisions	none
Classification Code	O2

ADR

14.1. UN-Number	UN1502
14.2. Proper shipping name	Sodium perchlorate
14.3. Hazard class	5.1
14.4. Packing group	II
Description	UN1502, Sodium perchlorate, 5.1, II, (E)
14.5. Environmental hazard.	None
14.6. Special Provisions	None
Classification Code	O2

ICAO

14.1. UN-Number	UN1502
14.2. Proper shipping name	Sodium perchlorate
14.3. Hazard class	5.1
14.4. Packing group	II
Description	UN1502, Sodium perchlorate, 5.1, II
14.5. Environmental hazard.	None
14.6. Special Provisions	None

IATA

14.1. UN-Number	UN1502
14.2. Proper Shipping Name	Sodium perchlorate

14.3. Hazard class	5.1
14.4. Packing group	II
Description	UN1502, Sodium perchlorate, 5.1, II
14.5. Environmental hazard.	None
14.6. Special Provisions	None
ERG Code	5L

Section 15. Regulatory information

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

International Inventories

TSCA	Substances comply or are exempt
EINECS/ELINCS	Substances comply or are exempt
DSL/NDSL	Substances comply or are exempt
PICCS	Substances comply or are exempt
ENCS	Substances comply or are exempt
IECSC	Substances comply or are exempt
AICS	Substances comply or are exempt
KECL	Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No information available

Section 16. Other information

Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H271 - May cause fire or explosion; strong oxidiser

Key literature references and sources for data

www.ChemADVISOR.com/

Issuing date 11-Apr-2017

Revision Date 11-Apr-2017

Revision Note Initial Release.

This safety data sheet complies with the requirements of Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No. 1907/2006

Disclaimer

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End of Safety Data Sheet

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. 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

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

1.2. Relevant identified uses of the substance or mixture and uses advised against

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

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Importer	Supplier
GenMark Diagnostics Europe GmbH	GenMark Diagnostics
Chollerstrasse 4	5964 La Place Court
6300 Zug	Carlsbad, CA 92008
Switzerland	USA
TEL: +41 41 530 6526	TEL: 1-800-373-6767

For further information, please contact

E-mail address info@genmarkdx.com

1.4. Emergency telephone number

Emergency Telephone Number 1-800-424-9300
 +1 703-527-3887 (Collect calls accepted)

Europe	112
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Section 2. Hazards identification

2.1. - Classification of the substance or mixture

REGULATION (EC) No 1272/2008

The product is not classified as dangerous according to Regulation (EC) No. 1272/2008.

Physical hazards

none

2.2. Label elements

The product is not classified as dangerous according to Regulation (EC) No. 1272/2008.

Signal Word none

2.3. Other information

None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Chemical Name	EC-No	CAS-No	Weight percent	EU - GHS Substance Classification	REACH No.
Polyethylene glycol	-	25322-68-3	10-15	-	no data available

For the full text of the H-Statements mentioned in this Section, see Section 16

Note

Substance(s) listed above that do not have an assigned classification are presented because there are applicable community exposure limits associated to them and they are above the standard regulatory threshold for reporting (see section 8 of the SDS for further information).

Section 4. First aid measures

4.1. Description of 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.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Consult a physician.
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.

4.2. Most important symptoms and effects, both acute and delayed

Most Important Symptoms/Effects None known.

4.3. Indication of immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

Section 5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media

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

Extinguishing Media Which Must not be Used for Safety Reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards Arising from the Substance or Preparation Itself, Combustion Products, Resulting Gases

Hydrogen chloride gas. Carbon oxides. Nitrogen oxides (NO_x). Sodium oxides.

5.3. Advice for firefighters

Special protective equipment for fire-fighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

Prevent further leakage or spillage if safe to do so.

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

6.4. Reference to other sections

See Section 12 for additional information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handling

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

Hygiene measures

Handle in accordance with good industrial hygiene and safety practise.

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end uses

Exposure scenario

No information available

Other Guidelines

No information available

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits

Chemical Name	European Union	Austria	Belgium	Cyprus	Denmark
Polyethylene glycol 25322-68-3		STEL: 4000 mg/m ³ TWA: 1000 mg/m ³			TWA: 1000 mg/m ³
Chemical Name	Finland	France	Germany	Gibraltar	Greece
Polyethylene glycol 25322-68-3			TWA: 1000 mg/m ³ Ceiling / Peak: 8000 mg/m ³ Repr*		
Chemical Name	Switzerland		Sweden	The United Kingdom	
Polyethylene glycol 25322-68-3	TWA: 1000 mg/m ³				

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering measures	Ensure adequate ventilation, especially in confined areas.
Personal protective equipment	Personal protection equipment should be chosen according to the CEN standards
Eye 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	Lightweight protective clothing.
Hand protection	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).

Environmental Exposure Controls No information available.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State	Liquid	Appearance	colourless
Odour	No information available		

Property	Values
pH	no data available
Melting point/range	no data available
Boiling point/boiling range	no data available
Flash point	no data available
Evaporation rate	no data available
Flammability (solid, gas)	no data available
Flammability Limits in Air	no data available
Vapour pressure	no data available
Vapour density	no data available
Relative density	no data available
Water solubility	no data available
Solubility in other solvents	no data available
Partition coefficient: n-octanol/water	no data available
Autoignition temperature	no data available
Decomposition temperature	no data available
Decomposition temperature	no data available
Viscosity	no data available
Explosive properties	No information available
Oxidising properties	No information available
9.2. Other information	
VOC Content (%)	No information available

Section 10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

None known based on information supplied.

Incompatible materials

Strong oxidising agents.

10.6. Hazardous decomposition products

May emit toxic fumes under fire conditions.

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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.

Sensitisation	No information available.
Mutagenic effects	No information available.
Carcinogenic effects	No information available.
Reproductive toxicity	No information available.
Developmental Toxicity	No information available.
Specific target organ systemic toxicity (single exposure)	No information available.
Specific target organ systemic toxicity (repeated exposure)	No information available.
Aspiration hazard	No information available.

Section 12. Ecological information

12.1. Toxicity

Ecotoxicity effects

Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia magna (Water flea)
Polyethylene glycol		LC50 24 h: > 5000 mg/L (Carassius auratus)	EC50 = 100000 mg/L 15 min	

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors

Section 13. Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14. Transport information

IMDG/IMO

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable.
14.5. Marine pollutant	None
14.6. Special Provisions	none
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

RID

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	none

ADR

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	Not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	None

ICAO

14.1. UN-Number	not regulated.
14.2. Proper shipping name	not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	None

IATA

14.1. UN-Number	not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	None

Section 15. Regulatory information

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

International Inventories

TSCA	Complies
EINECS/ELINCS	Substances comply or are exempt
DSL/NDSL	Substances comply or are exempt
PICCS	Substances comply or are exempt
ENCS	Substances comply or are exempt
IECSC	Substances comply or are exempt
AICS	Substances comply or are exempt
KECL	Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No information available

Section 16. Other information

Key literature references and sources for data

www.ChemADVISOR.com/

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

This safety data sheet complies with the requirements of Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No. 1907/2006

Disclaimer

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ePlex®, eSensor®, GenMark®, GenMark Dx® and XT-8® are trademarks of GenMark Diagnostics, Inc.

End of Safety Data Sheet

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. 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

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

Contains Guanidine hydrochloride

1.2. Relevant identified uses of the substance or mixture and uses advised against

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

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Importer	Supplier
GenMark Diagnostics Europe GmbH	GenMark Diagnostics
Chollerstrasse 4	5964 La Place Court
6300 Zug	Carlsbad, CA 92008
Switzerland	USA
TEL: +41 41 530 6526	TEL: 1-800-373-6767

For further information, please contact

E-mail address info@genmarkdx.com

1.4. Emergency telephone number

Emergency Telephone Number 1-800-424-9300
+1 703-527-3887 (Collect calls accepted)

Europe	112
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Section 2. Hazards identification

2.1. - Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Acute oral toxicity	Category 4
Skin corrosion/irritation	Category 2

Serious eye damage/eye irritation	Category 2
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Physical hazards

none

2.2. Label elements



Signal Word

Warning

Hazard statements

- H302 - Harmful if swallowed
- H315 - Causes skin irritation
- H319 - Causes serious eye irritation

Precautionary statements

- P270 - Do not eat, drink or smoke when using this product
- P264 - Wash face, hands and any exposed skin thoroughly after handling
- P301 + P312 - IF SWALLOWED: Call a POISON centre or doctor/ physician if you feel unwell
- P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
- P362 - Take off contaminated clothing and wash before reuse
- P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

2.3. Other information

Harmful to aquatic life

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Chemical Name	EC-No	CAS-No	Weight percent	EU - GHS Substance Classification	REACH No.
Urea	200-315-5	57-13-6	25-50		no data available
Guanidine hydrochloride	200-002-3	50-01-1	25-50	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	no data available
Sodium lauryl sulfate	205-788-1	151-21-3	<2		no data available

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1. Description of first aid measures

General advice	Do not get in eyes, on skin, or on clothing. Show this safety data sheet to the doctor in attendance.
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.
Ingestion	Call a POISON CENTRE 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.
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.
Protection of first-aiders	Use personal protective equipment.

4.2. Most important symptoms and effects, both acute and delayed

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

4.3. Indication of immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

Section 5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media

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

Extinguishing Media Which Must not be Used for Safety Reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards Arising from the Substance or Preparation Itself, Combustion Products, Resulting Gases

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

5.3. Advice for firefighters

Special protective equipment for fire-fighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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.

6.2. Environmental precautions

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

6.3. Methods and materials for containment and cleaning up

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

6.4. Reference to other sections

See Section 12 for additional information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handling

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

Hygiene measures

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

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end uses

Exposure scenario

No information available

Other Guidelines

No information available

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits

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

Chemical Name	Ireland	Italy	Lithuania	Luxembourg	Malta
Urea 57-13-6			TWA: 10 mg/m ³		
Chemical Name	The Netherlands	Norway	Poland	Portugal	Spain
Urea 57-13-6		TWA: 30 µg Hg/g Creatinine STEL: 30 µg Hg/g Creatinine			

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific

regulatory bodies

Derived No Effect Level No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering measures Ensure adequate ventilation, especially in confined areas.
Personal protective equipment Personal protection equipment should be chosen according to the CEN standards
Eye 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 Long sleeved clothing.
Hand protection Protective 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).

Environmental Exposure Controls Do not allow material to contaminate ground water system.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State	Liquid	Appearance	colourless
Odour	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
Evapouration rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limits in Air	no data available	None known
Vapour pressure	no data available	None known
Vapour density	no data available	None known
Relative density	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
Decomposition temperature	no data available	None known
Viscosity	no data available	None known

Explosive properties No information available
Oxidising properties No information available

9.2. Other information

VOC Content (%) No information available

Section 10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

None known based on information supplied.

Incompatible materials

Strong oxidising agents.

10.6. Hazardous decomposition products

May emit toxic fumes under fire conditions.

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

Sensitisation

Did not cause sensitisation on laboratory animals.

Mutagenic effects

In vitro tests did not show mutagenic effects.

Carcinogenic effects

Contains no ingredient listed as a carcinogen.

Reproductive toxicity

No information available.

Developmental Toxicity

No information available.

Specific target organ systemic toxicity (single exposure)

No information available.

Specific target organ systemic toxicity (repeated exposure)

No information available.

Target Organ Effects

Skin. Eyes. Gastrointestinal tract (GI). Liver. Blood.

Aspiration hazard

No information available.

Section 12. Ecological information

12.1. Toxicity

Ecotoxicity effects

Harmful to aquatic organisms.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia magna (Water flea)
Urea		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)
Guanidine hydrochloride		LC50 48 h: = 1758 mg/L (Leuciscus idus)	EC50 = 88.7 mg/L 18 h	
Sodium lauryl sulfate	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)

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

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

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors

Section 13. Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.
Other Information	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

Section 14. Transport information

IMDG/IMO

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable.
14.5. Marine pollutant	None
14.6. Special Provisions	none
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

RID

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None

14.6. Special Provisions none

ADR

14.1. UN-Number not regulated.
14.2. Proper shipping name Not regulated.
14.3. Hazard class Not regulated.
14.4. Packing group not regulated.
Description Not applicable
14.5. Environmental hazard. None
14.6. Special Provisions None

ICAO

14.1. UN-Number not regulated.
14.2. Proper shipping name not regulated.
14.3. Hazard class not regulated.
14.4. Packing group not regulated.
Description Not applicable
14.5. Environmental hazard. None
14.6. Special Provisions None

IATA

14.1. UN-Number not regulated.
14.2. Proper Shipping Name Not regulated.
14.3. Hazard class not regulated.
14.4. Packing group not regulated.
Description Not applicable
14.5. Environmental hazard. None
14.6. Special Provisions None

Section 15. Regulatory information

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

International Inventories

TSCA	Substances comply or are exempt
EINECS/ELINCS	Substances comply or are exempt
DSL/NDSL	Substances comply or are exempt
PICCS	Substances comply or are exempt
ENCS	Substances comply or are exempt
IECSC	Substances comply or are exempt
AICS	Substances comply or are exempt
KECL	Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No information available

Section 16. Other information

Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

Key literature references and sources for data

www.ChemADVISOR.com/

Issuing date 11-Apr-2017

Revision Date 11-Apr-2017

Revision Note Initial Release.

This safety data sheet complies with the requirements of Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No. 1907/2006

Disclaimer

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End of Safety Data Sheet

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. 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

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

1.2. Relevant identified uses of the substance or mixture and uses advised against

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

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Importer	Supplier
GenMark Diagnostics Europe GmbH	GenMark Diagnostics
Chollerstrasse 4	5964 La Place Court
6300 Zug	Carlsbad, CA 92008
Switzerland	USA
TEL: +41 41 530 6526	TEL: 1-800-373-6767

For further information, please contact

E-mail address info@genmarkdx.com

1.4. Emergency telephone number

Emergency Telephone Number 1-800-424-9300
+1 703-527-3887 (Collect calls accepted)

Europe	112
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Section 2. Hazards identification

2.1. - Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Not classified

Physical hazards

none

2.2. Label elements

Not classified

Signal Word none

2.3. Other information

None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

3.2. Not applicable

Chemical Name	EC-No	CAS-No	Weight percent	EU - GHS Substance Classification	REACH No.
Poly[oxy(dimethylsilylene)]	-	9016-00-6	>95		no data available

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1. Description of 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.

Ingestion Clean mouth with water and afterwards drink plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Consult a physician.

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.

4.2. Most important symptoms and effects, both acute and delayed

Most Important Symptoms/Effects None known.

4.3. Indication of immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

Section 5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media

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

Extinguishing Media Which Must not be Used for Safety Reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards Arising from the Substance or Preparation Itself, Combustion Products, Resulting Gases

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

5.3. Advice for firefighters

Special protective equipment for fire-fighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

Prevent further leakage or spillage if safe to do so.

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

6.4. Reference to other sections

See Section 12 for additional information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handling

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

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.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat.

7.3. Specific end uses

Exposure scenario

No information available

Other Guidelines

No information available

Section 8. Exposure controls/personal protection

8.1. Control parameters

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

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering measures	Ensure adequate ventilation, especially in confined areas.
Personal protective equipment	Personal protection equipment should be chosen according to the GEN standards
Eye 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.
Hand protection	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).

Environmental Exposure Controls No information available.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State	Liquid	Appearance	Clear. viscous
Odour	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	no data available	None known
Vapour pressure	no data available	None known
Vapour density	no data available	None known

Relative density	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
Decomposition temperature	no data available	None known
Viscosity	5 cSt	None known

Explosive properties No information available
Oxidising properties No information available

9.2. Other information

VOC Content (%) No information available

Section 10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Heat, flames and sparks.

Incompatible materials

Oxidising agents.

10.6. Hazardous decomposition products

Formaldehyde. Organic acids. Silicon dioxide.

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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
Poly[oxy(dimethylsilylene)]	> 40000 mg/kg (rat)		>535 mg/L (rat)

Skin corrosion/irritation

Not classified

Eye damage/irritation

Not classified

Sensitisation

Not classified

Mutagenic effects

Based on available data, the classification criteria are not met.

Carcinogenic effects

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.
Specific target organ systemic toxicity (single exposure)	Based on available data, the classification criteria are not met
Specific target organ systemic toxicity (repeated exposure)	Based on available data, the classification criteria are not met
Aspiration hazard	None of the ingredients are known to be an aspiration hazard.

Section 12. Ecological information

12.1. Toxicity

Ecotoxicity effects

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)]		LC50 96 h: > 10000 mg/L static (Lepomis macrochirus) LC50 96 h: > 10000 mg/L static (Oncorhynchus mykiss)		

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors

Section 13. Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14. Transport information

IMDG/IMO

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable.
14.5. Marine pollutant	None
14.6. Special Provisions	none
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

RID

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	none

ADR

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	Not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	None

ICAO

14.1. UN-Number	not regulated.
14.2. Proper shipping name	not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	None

IATA

14.1. UN-Number	not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	None

Section 15. Regulatory information

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

International Inventories

TSCA	Substances comply or are exempt
EINECS/ELINCS	Substances comply or are exempt
DSL/NDSL	Substances comply or are exempt
PICCS	Substances comply or are exempt
ENCS	Substances comply or are exempt
IECSC	Substances comply or are exempt
AICS	Substances comply or are exempt
KECL	Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No information available

Section 16. Other information

Key literature references and sources for data

www.ChemADVISOR.com/

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

This safety data sheet complies with the requirements of Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No. 1907/2006

Disclaimer

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ePlex®, eSensor®, GenMark®, GenMark Dx® and XT-8® are trademarks of GenMark Diagnostics, Inc.

End of Safety Data Sheet

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. 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

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

1.2. Relevant identified uses of the substance or mixture and uses advised against

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

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Importer	Supplier
GenMark Diagnostics Europe GmbH	GenMark Diagnostics
Chollerstrasse 4	5964 La Place Court
6300 Zug	Carlsbad, CA 92008
Switzerland	USA
TEL: +41 41 530 6526	TEL: 1-800-373-6767

For further information, please contact

E-mail address info@genmarkdx.com

1.4. Emergency telephone number

Emergency Telephone Number 1-800-424-9300
 +1 703-527-3887 (Collect calls accepted)

Europe	112
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Section 2. Hazards identification

2.1. - Classification of the substance or mixture

REGULATION (EC) No 1272/2008

The product is not classified as dangerous according to Regulation (EC) No. 1272/2008.

Physical hazards

none

2.2. Label elements

The product is not classified as dangerous according to Regulation (EC) No. 1272/2008.

Signal Word none

2.3. Other information

None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Chemical Name	EC-No	CAS-No	Weight percent	EU - GHS Substance Classification	REACH No.
Sodium azide	247-852-1	26628-22-8	0.1-1	Acute Tox. 2 (H300) (EUH032) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	no data available

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1. Description of 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.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Consult a physician.
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.

4.2. Most important symptoms and effects, both acute and delayed

Most Important Symptoms/Effects None known.

4.3. Indication of immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

Section 5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media

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

Extinguishing Media Which Must not be Used for Safety Reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards Arising from the Substance or Preparation Itself, Combustion Products, Resulting Gases

Hydrogen chloride gas. Carbon oxides. Nitrogen oxides (NO_x). Sodium oxides.

5.3. Advice for firefighters

Special protective equipment for fire-fighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

Prevent further leakage or spillage if safe to do so.

Soak up with inert absorbent material. Pick up and transfer to properly labelled containers. Keep in suitable, 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.

6.4. Reference to other sections

See Section 12 for additional information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handling

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

Hygiene measures

Handle in accordance with good industrial hygiene and safety practise.

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end uses

Exposure scenario

No information available

Other Guidelines

No information available

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits

Chemical Name	European Union	Austria	Belgium	Cyprus	Denmark
Sodium azide 26628-22-8	S* TWA 0.1 mg/m ³ STEL 0.3 mg/m ³	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ Skin	MLV: 0.3 mg/m ³ MLV: 0.1 mg/m ³ Skin	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	TWA: 0.1 mg/m ³ Skin
Chemical Name	Finland	France	Germany	Gibraltar	Greece
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	TWA: 0.2 mg/m ³ Ceiling / Peak: 0.4 mg/m ³ Repr*	STEL: 0.3 mg/m ³ TWA: 0.1 mg/m ³ Skin	TWA: 0.1 ppm TWA: 0.3 mg/m ³ STEL: 0.1 ppm STEL: 0.3 mg/m ³
Chemical Name	Ireland	Italy	Lithuania	Luxembourg	Malta
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin Carc*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin Acute*		
Chemical Name	The Netherlands	Norway	Poland	Portugal	Spain
Sodium azide 26628-22-8	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	TWA: 0.1 mg/m ³ STEL: 0.1 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Ceiling: 0.29 mg/m ³ Ceiling: 0.11 ppm Skin Carc*	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin
Chemical Name	Switzerland		Sweden	The United Kingdom	
Sodium azide 26628-22-8	STEL: 0.4 mg/m ³ TWA: 0.2 mg/m ³		LLV: 0.1 mg/m ³ Binding STLV: 0.3 mg/m ³	TWA: 0.1 mg/m ³ STEL: 0.3 mg/m ³ Skin	

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering measures

Ensure adequate ventilation, especially in confined areas.

Personal protective equipment

Personal protection equipment should be chosen according to the CEN standards

Eye 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

Lightweight protective clothing.

Hand protection

Please observe the instructions regarding permeability and breakthrough time which are

Respiratory protection

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. 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).

Environmental Exposure Controls No information available.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State	Liquid	Appearance	colourless
Odour	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	no data available	None known
Vapour pressure	no data available	None known
Vapour density	no data available	None known
Relative density	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
Decomposition temperature	no data available	None known
Viscosity	no data available	None known

Explosive properties	No information available
Oxidising properties	No information available

9.2. Other information

VOC Content (%)	No information available
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Section 10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. 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 oxidising agents.

10.6. Hazardous decomposition products

May emit toxic fumes under fire conditions.

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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.

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

Sensitisation	No information available.
Mutagenic effects	No information available.
Carcinogenic effects	No information available.
Reproductive toxicity	No information available.
Developmental Toxicity	No information available.
Specific target organ systemic toxicity (single exposure)	No information available.
Specific target organ systemic toxicity (repeated exposure)	No information available.
Aspiration hazard	No information available.

Section 12. Ecological information

12.1. Toxicity

Ecotoxicity effects

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		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)		

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors

Section 13. Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14. Transport information

IMDG/IMO

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable.
14.5. Marine pollutant	None
14.6. Special Provisions	none
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

RID

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable

14.5. Environmental hazard.	None
14.6. Special Provisions	none

ADR

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	Not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	None

ICAO

14.1. UN-Number	not regulated.
14.2. Proper shipping name	not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	None

IATA

14.1. UN-Number	not regulated.
14.2. Proper Shipping Name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable
14.5. Environmental hazard.	None
14.6. Special Provisions	None

Section 15. Regulatory information

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

International Inventories

TSCA	Substances comply or are exempt
EINECS/ELINCS	Substances comply or are exempt
DSL/NDSL	Substances comply or are exempt
PICCS	Substances comply or are exempt
ENCS	Substances comply or are exempt
IECSC	Substances comply or are exempt
AICS	Substances comply or are exempt
KECL	Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No information available

Section 16. Other information

Full text of H-Statements referred to under sections 2 and 3

H300 - Fatal if swallowed

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

EUH032 - Contact with acids liberates very toxic gas

Key literature references and sources for data

www.ChemADVISOR.com/

Issuing date 11-Apr-2017

Revision Date 11-Apr-2017

Revision Note Initial Release.

This safety data sheet complies with the requirements of Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No. 1907/2006

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

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. 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

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

1.2. Relevant identified uses of the substance or mixture and uses advised against

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

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Importer	Supplier
GenMark Diagnostics Europe GmbH	GenMark Diagnostics
Chollerstrasse 4	5964 La Place Court
6300 Zug	Carlsbad, CA 92008
Switzerland	USA
TEL: +41 41 530 6526	TEL: 1-800-373-6767

For further information, please contact

E-mail address info@genmarkdx.com

1.4. Emergency telephone number

Emergency Telephone Number 1-800-424-9300
 +1 703-527-3887 (Collect calls accepted)

Europe	112
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Section 2. Hazards identification

2.1. - Classification of the substance or mixture

REGULATION (EC) No 1272/2008

The product is not classified as dangerous according to Regulation (EC) No. 1272/2008.

Physical hazards

none

2.2. Label elements

The product is not classified as dangerous according to Regulation (EC) No. 1272/2008.

Signal Word none

2.3. Other information

None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

The product is not classified as dangerous according to Regulation (EC) No. 1272/2008. The product contains no substances classified as hazardous to health in concentrations which should be taken into account according to EC directives.

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1. Description of 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.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Consult a physician.
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.

4.2. Most important symptoms and effects, both acute and delayed

Most Important Symptoms/Effects None known.

4.3. Indication of immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

Section 5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media

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

Extinguishing Media Which Must not be Used for Safety Reasons

No information available.

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards Arising from the Substance or Preparation Itself, Combustion Products, Resulting Gases

Hydrogen chloride gas. Carbon oxides. Nitrogen oxides (NO_x). Sodium oxides.

5.3. Advice for firefighters

Special protective equipment for fire-fighters

As in any fire, wear self-contained breathing apparatus and full protective gear.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

Prevent further leakage or spillage if safe to do so.

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

6.4. Reference to other sections

See Section 12 for additional information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handling

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

Hygiene measures

Handle in accordance with good industrial hygiene and safety practise.

7.2. Conditions for safe storage, including any incompatibilities

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

7.3. Specific end uses

Exposure scenario

No information available

Other Guidelines

No information available

Section 8. Exposure controls/personal protection

8.1. Control parameters

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

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering measures	Ensure adequate ventilation, especially in confined areas.
Personal protective equipment	Personal protection equipment should be chosen according to the CEN standards
Eye 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	Lightweight protective clothing.
Hand protection	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).

Environmental Exposure Controls No information available.

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State	Liquid	Appearance	colourless
Odour	No information available		

Property	Values	Remarks/ - Method
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	no data available	None known
Vapour pressure	no data available	None known
Vapour density	no data available	None known
Relative density	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
Decomposition temperature	no data available	None known
Viscosity	no data available	None known

Explosive properties No information available
Oxidising properties No information available

9.2. Other information

VOC Content (%) No information available

Section 10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

None known based on information supplied.

Incompatible materials

Strong oxidising agents.

10.6. Hazardous decomposition products

May emit toxic fumes under fire conditions.

Section 11. Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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.

Sensitisation

No information available.

Mutagenic effects

No information available.

Carcinogenic effects

No information available.

Reproductive toxicity

No information available.

Developmental Toxicity

No information available.

Specific target organ systemic toxicity (single exposure)

No information available.

Specific target organ systemic toxicity (repeated exposure)

No information available.

Aspiration hazard No information available.

Section 12. Ecological information

12.1. Toxicity

Ecotoxicity effects

Contains no substances known to be hazardous to the environment or not degradable in waste water treatment plants.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

No information available.

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

This product does not contain any known or suspected endocrine disruptors

Section 13. Disposal considerations

13.1. Waste treatment methods

Waste from residues / unused products

Dispose of in accordance with local regulations.

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14. Transport information

IMDG/IMO

14.1. UN-Number	not regulated.
14.2. Proper shipping name	Not regulated.
14.3. Hazard class	not regulated.
14.4. Packing group	not regulated.
Description	Not applicable.
14.5. Marine pollutant	None

14.6. Special Provisions none
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available

RID

14.1. UN-Number not regulated.
14.2. Proper shipping name Not regulated.
14.3. Hazard class not regulated.
14.4. Packing group not regulated.
Description Not applicable
14.5. Environmental hazard. None
14.6. Special Provisions none

ADR

14.1. UN-Number not regulated.
14.2. Proper shipping name Not regulated.
14.3. Hazard class Not regulated.
14.4. Packing group not regulated.
Description Not applicable
14.5. Environmental hazard. None
14.6. Special Provisions None

ICAO

14.1. UN-Number not regulated.
14.2. Proper shipping name not regulated.
14.3. Hazard class not regulated.
14.4. Packing group not regulated.
Description Not applicable
14.5. Environmental hazard. None
14.6. Special Provisions None

IATA

14.1. UN-Number not regulated.
14.2. Proper Shipping Name Not regulated.
14.3. Hazard class not regulated.
14.4. Packing group not regulated.
Description Not applicable
14.5. Environmental hazard. None
14.6. Special Provisions None

Section 15. Regulatory information

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

International Inventories

TSCA	Substances comply or are exempt
EINECS/ELINCS	Substances comply or are exempt
DSL/NDSL	Substances comply or are exempt
PICCS	Substances comply or are exempt
ENCS	Substances comply or are exempt
IECSC	Substances comply or are exempt
AICS	Substances comply or are exempt
KECL	Substances comply or are exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

15.2. Chemical Safety Assessment

No information available

Section 16. Other information

Key literature references and sources for data

www.ChemADVISOR.com/

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This safety data sheet complies with the requirements of Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No. 1907/2006

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End of Safety Data Sheet