

# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
US - OSHA Hazard Communication Standard (29 CFR 1910.1200)

Issuing Date 29-Sep-2021

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Revision Number 1

## 1. Identification

### Product identifier

**Product Name** Lysis Component for: ePlex® Respiratory Pathogen Panel and Respiratory Pathogen Panel 2

### Other means of identification

**Product Code(s)** EA001012, KT022725, EA001212, KT022472, EA001222, KT022740, EA001232, KT022728

**Synonyms** Respiratory Pathogen Panel and Respiratory Pathogen Panel 2

### Recommended use of the chemical and restrictions on use

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

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

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

**E-mail** CustomerService@genmarkdx.com

### Emergency telephone number

**Emergency telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

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

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 1

### Hazards not otherwise classified (HNOC)

Not applicable.

### Label elements

**Danger**

**Hazard statements**

Harmful if swallowed.  
Causes skin irritation.  
Causes serious eye damage.



**Precautionary Statements - Prevention**

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

**Precautionary Statements - Response**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
Immediately call a POISON CENTER or doctor  
IF ON SKIN: Wash with plenty of water and soap  
If skin irritation occurs: Get medical advice/attention  
Take off contaminated clothing and wash it before reuse  
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell  
Rinse mouth

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other information**

May be harmful if inhaled.

**3. Composition/information on ingredients**

**Substance**

Not applicable.

**Mixture**

**Synonyms**

Respiratory Pathogen Panel and Respiratory Pathogen Panel 2

Chemical name	CAS No	Weight-%	Trade secret
Guanidinium chloride	50-01-1	25-50	*
Sodium dodecyl sulphate	151-21-3	1-5	*

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

**4. First-aid measures**

**Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.
<b>Inhalation</b>	Remove to fresh air. Get medical attention immediately if symptoms occur.
<b>Eye contact</b>	Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a physician.
<b>Self-protection of the first aider</b>	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

**Most important symptoms and effects, both acute and delayed**

**Symptoms** Burning sensation. May cause redness and tearing of the eyes.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians** Treat symptomatically.

**5. Fire-fighting measures**

<b>Suitable Extinguishing Media</b>	Water spray, carbon dioxide (CO <sub>2</sub> ), dry chemical, alcohol-resistant foam. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media</b>	None known based on information supplied.
<b>Specific hazards arising from the chemical</b>	None known based on information supplied.
<b>Hazardous combustion products</b>	Hydrogen chloride gas. Carbon oxides. Nitrogen oxides (NO <sub>x</sub> ). Sodium oxides.
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	None.
<b>Sensitivity to static discharge</b>	None.
<b>Special protective equipment and precautions for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

**6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Ensure adequate ventilation. Avoid breathing vapors or mists. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. See section 8 for more information.

**Other information** Refer to protective measures listed in Sections 7 and 8.

**Methods and material for containment and cleaning up**

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

**Methods for cleaning up** Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

Keep in suitable, closed containers for disposal.

## 7. Handling and storage

### Precautions for safe handling

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

### Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.

## 8. Exposure controls/personal protection

### 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.

### Appropriate engineering controls

**Engineering controls** Showers  
Eyewash stations  
Ventilation systems.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** Tight sealing safety goggles.

**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.

**Skin and body protection** Wear suitable protective clothing. Long sleeved clothing.

**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).

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

#### Appearance

Physical state

Liquid

Color

Colorless

Odor

No data available

**Odor threshold** No data available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>		No data available
None known		<b>Melting point / freezing point</b>
No data available		<b>Initial boiling point and boiling range</b>
No data available		<b>Flash point</b>
No data available		<b>Evaporation rate</b>
No data available		<b>Flammability</b>
No data available		<b>Flammability Limit in Air</b>
		<b>Upper flammability or explosive limits</b>
No data available		<b>Lower flammability or explosive limits</b>
No data available		<b>Vapor pressure</b>
No data available		<b>Vapor density</b>
No data available		<b>Relative density</b>
No data available		<b>Water solubility</b>
No data available		<b>Solubility(ies)</b>
		<b>Partition coefficient</b>
No data available		<b>Autoignition temperature</b>
No data available		<b>Decomposition temperature</b>
No data available		<b>Kinematic viscosity</b>
No data available		<b>Dynamic viscosity</b>
<b><u>Other information</u></b>		
<b>Explosive properties</b>	No information available	
<b>Oxidizing properties</b>	No information available	
<b>Softening point</b>	No information available	
<b>Molecular weight</b>	No information available	
<b>VOC Content (%)</b>	No information available	
<b>Liquid Density</b>	No information available	
<b>Bulk density</b>	No information available	

**10. Stability and reactivity**

<b>Reactivity</b>	None under normal use conditions.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	May emit toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract. May be harmful if inhaled.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Causes serious eye damage. (based on components). May cause irreversible damage to eyes.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on components).

### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Redness. Burning. May cause blindness. May cause redness and tearing of the eyes.

### Acute toxicity

#### Numerical measures of toxicity

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

ATEmix (oral) 1,186.20 mg/kg

#### Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Guanidinium chloride 50-01-1	= 475 mg/kg ( Rat )	> 2000 mg/kg ( Rabbit )	3.181 mg/l (Rat) 4h
Sodium dodecyl sulphate 151-21-3	= 1288 mg/kg ( Rat )	= 200 mg/kg ( Rabbit )	> 3900 mg/m <sup>3</sup> ( Rat ) 1 h

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

<b>Skin corrosion/irritation</b>	Classification based on data available for ingredients. Irritating to skin.
<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Causes burns. Risk of serious damage to eyes.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.

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

**Other adverse effects** No information available.

**Interactive effects** No information available.

## 12. Ecological information

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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium dodecyl sulphate 151-21-3	EC50: 3.59 - 15.6mg/L (96h, Pseudokirchneriella subcapitata) EC50: 30 - 100mg/L (96h, Desmodemus subspicatus) EC50: =117mg/L (96h, Pseudokirchneriella subcapitata) EC50: =53mg/L (72h, Desmodemus subspicatus)	LC50: 15 - 18.9mg/L (96h, Pimephales promelas)	-	EC50 48 h: = 1.8 mg/L (Daphnia magna)

**Persistence and degradability** No information available.

**Bioaccumulation**

### Component Information

Chemical name	Partition coefficient
Guanidinium chloride 50-01-1	-1.7
Sodium dodecyl sulphate 151-21-3	1.6

**Other adverse effects** No information available.

## 13. Disposal considerations

### Waste treatment methods

**Waste from residues/unused products** Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

## 14. Transport information

**DOT** Not regulated

**IATA** Not regulated

**IMDG** Not regulated

**15. Regulatory information**

**International Inventories**

Contact supplier for inventory compliance status

**US Federal Regulations**

**SARA 313**

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

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

**CWA (Clean Water Act)**

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

**CERCLA**

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

**US State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Water 7732-18-5	-	-	X

**U.S. EPA Label Information**

EPA Pesticide Registration Number Not applicable

**16. Other information**

<b>NFPA</b>	Health hazards 3	Flammability 0	Instability 0	Special hazards -
<b>HMIS</b>	Health hazards 3	Flammability 0	Physical hazards 0	Personal protection X

**Key or legend to abbreviations and acronyms used in the safety data sheet**

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation



**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
U.S. Environmental Protection Agency ChemView Database  
European Food Safety Authority (EFSA)  
EPA (Environmental Protection Agency)  
Acute Exposure Guideline Level(s) (AEGL(s))  
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

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**Revision Note** Initial Release.

**Disclaimer**

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given 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. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

**End of Safety Data Sheet**