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 01-Oct-2021 **Revision Date** 01-Oct-2021 **Revision Number** 1

1. Identification

Product identifier

Product Name Detection/Salting 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

UN/ID no UN1502

Synonyms 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
Acute toxicity - Dermal	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Oxidizing solids	Category 2

Hazards not otherwise classified (HNOC)
Not applicable.

Label elements

Danger

Hazard statements
May intensify fire; oxidizer.
Harmful if swallowed.
Harmful in contact with skin.
Causes skin irritation.
Causes serious eye irritation.

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Keep away from heat
Keep/Store away from clothing/ combustible materials
Take any precaution to avoid mixing with combustibles
Wear protective gloves/protective clothing/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
If eye irritation persists: Get medical advice/attention
IF ON SKIN: Wash with plenty of water and soap
Call a POISON CENTER or doctor if you feel unwell
Take off contaminated clothing and wash it before reuse
If skin irritation occurs: Get medical advice/attention
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
Rinse mouth
In case of fire: Use carbon dioxide, alcohol-resistant foam, or water spray to extinguish

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

Other information
No information available.

Unknown acute toxicity
59 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
66 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Synonyms Respiratory Pathogen Panel 2

Chemical name	CAS No	Weight-%	Trade secret
Guanidine hydrochloride	50-01-1	30-40	*
Sodium perchlorate	7601-89-0	5-10	*
Ethyl alcohol	64-17-5	< 1	*

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

4. First-aid measures

Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Skin contact IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes. IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse. Wash off immediately with soap and plenty of water for at least 15 minutes. If symptoms persist, call a physician.

Ingestion Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a physician.

Self-protection of the first aider Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

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

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media Water. Carbon dioxide (CO2). Alcohol resistant foam. Flood fire area with water from a distance. Move containers from fire area if you can do it without risk. Cool containers with flooding quantities of water until well after fire is out.

Unsuitable extinguishing media Dry chemical.

Specific hazards arising from the chemical These substances will accelerate burning when involved in a fire. Some may decompose explosively when heated or involved in a fire. May ignite combustibles (wood paper, oil, clothing, etc.). Runoff may create fire or explosion hazard.

Hazardous combustion products Hydrogen chloride gas. Sodium oxides. Carbon oxides. Nitrogen oxides (NOx).

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge	Yes.
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. Do not move cargo or vehicle if cargo has been exposed to heat. Oxidizer. May ignite combustibles (wood paper, oil, clothing, etc.). Move containers from fire area if you can do it without risk. Fight fire from maximum distance or use unmanned hose holders or monitor nozzles. ALWAYS stay away from tanks engulfed in fire. For massive fire, use unmanned hose holders or monitor nozzles; if this is impossible withdraw from area and let fire burn.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. See section 8 for more information. Stop leak if you can do it without risk. Use personal protective equipment as required.
Other information	Keep combustibles (wood, paper, oil, etc) away from spilled material. DO NOT GET WATER INSIDE CONTAINERS. Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Stop leak if you can do it without risk. Cover with DRY earth, DRY sand or other non-combustible material followed with plastic sheet to minimize spreading or contact with rain.
Methods for cleaning up	Pick up and transfer to properly labeled containers. Avoid generation of dust. Do not dry sweep dust. Wet dust with water before sweeping or use a vacuum to collect dust. Keep in suitable, closed containers for disposal.

7. Handling and storage

Precautions for safe handling

Advice on safe handling	Use personal protection equipment. Avoid contact with skin, eyes or clothing. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Use with local exhaust ventilation. Handle in accordance with good industrial hygiene and safety practice. Take off contaminated clothing and wash before reuse. Avoid generation of dust.

Conditions for safe storage, including any incompatibilities

Storage Conditions	Keep containers tightly closed in a dry, cool and well-ventilated place. Keep in properly labeled containers. Do not store near combustible materials. Store in accordance with the particular national regulations. Store in accordance with local regulations.

8. Exposure controls/personal protection

Control parameters

Exposure Limits	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH
Ethyl alcohol 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m^3 (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m^3	IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m^3

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or 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. Chemical resistant apron. Wear fire/flame resistant/retardant 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 Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance Grayish white, Solid (compressed)
Physical state Solid
Color Grayish white
Odor Pungent
Odor threshold No data available

Property	Values	Remarks • Method
pH		No data available
Melting point / freezing point		No data available
Initial boiling point and boiling range		No data available
Flash point		No data available
Evaporation rate		No data available
Flammability		No data available
Flammability Limit in Air		

Upper flammability or explosive limits	No data available
Lower flammability or explosive limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available

Other information

Explosive properties	No information available
Oxidizing properties	Oxidizer
Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity Oxidizer.

Chemical stability May cause fire or explosion; strong oxidizer.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid Heat, flames and sparks. Incompatible materials.

Incompatible materials Organic material. Finely powdered metals. Forms shock-sensitive mixtures with other materials including powdered metals and magnesium.

Hazardous decomposition products May emit toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.

Skin contact Specific test data for the substance or mixture is not available. Causes skin irritation. Harmful in contact with skin. (based on components).

Ingestion 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. 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) 479.10 mg/kg
ATEmix (dermal) 2,000.00 mg/kg

Unknown acute toxicity

59 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
66 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Guanidine hydrochloride 50-01-1	= 475 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	= 3.181 mg/L (Rat) 4 h = 7.655 mg/L (Rat) 4 h
Sodium perchlorate 7601-89-0	= 2100 mg/kg (Rat)	-	-
Ethyl alcohol 64-17-5	= 7060 mg/kg (Rat)	-	= 116.9 mg/L (Rat) 4 h = 133.8 mg/L (Rat) 4 h

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

Skin corrosion/irritation Classification based on data available for ingredients. Irritating to skin.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity In vitro tests did not show mutagenic effects.

Carcinogenicity Ethanol has been shown to be carcinogenic in long-term studies only when consumed as alcoholic beverage. Contains no ingredients above reportable quantities listed as a carcinogen.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Ethyl alcohol 64-17-5	A3	Group 1	Known	X

Legend

ACGIH (American Conference of Governmental Industrial Hygienists)
A3 - Animal Carcinogen
IARC (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans
NTP (National Toxicology Program)
Known - Known Carcinogen
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

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
Ethyl alcohol 64-17-5	-	LC50: 12.0 - 16.0mL/L (96h, Oncorhynchus mykiss) LC50: 13400 - 15100mg/L (96h, Pimephales promelas) LC50: >100mg/L (96h, Pimephales promelas)	-	LC50: 9268 - 14221mg/L (48h, Daphnia magna) EC50: =2mg/L (48h, Daphnia magna)

Persistence and degradability No information available.

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Guanidine hydrochloride 50-01-1	-1.7
Ethyl alcohol 64-17-5	-0.32

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

California Hazardous Waste Status This product contains one or more substances that are listed with the State of California as a hazardous waste.

14. Transport information

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

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

DOT

UN/ID no UN1502

Proper shipping name	SODIUM PERCHLORATE
Transport hazard class(es)	5.1
Packing group	II
Special Provisions	IB6, IP2, T3, TP33
DOT Marine Pollutant	NP
Description	UN1502, SODIUM PERCHLORATE, 5.1, II
Emergency Response Guide Number	140

IATA

UN number or ID number	UN1502
UN proper shipping name	Sodium perchlorate
Transport hazard class(es)	5.1
Packing group	II
Description	UN1502, Sodium perchlorate, 5.1, II
ERG Code	5L

IMDG

UN number or ID number	UN1502
UN proper shipping name	SODIUM PERCHLORATE
Transport hazard class(es)	5.1
Packing group	II
EmS-No	F-H, S-Q
Marine pollutant	NP
Description	UN1502, SODIUM PERCHLORATE, 5.1, II

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

Ethyl alcohol is only considered a Proposition 65 developmental hazard when it is ingested as an alcoholic beverage. This product contains the following Proposition 65 chemicals:

Chemical name	California Proposition 65
Ethyl alcohol - 64-17-5	Carcinogen Developmental

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Sodium perchlorate 7601-89-0	X	X	X
Ethyl alcohol 64-17-5	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA	**Health hazards** 2	**Flammability** 0	**Instability** 1	**Special hazards** OX
HMIS	**Health hazards** 2	**Flammability** 0	**Physical hazards** 1	**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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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