

Safety Data Sheet

Custom AccuPlex JRCLA

Doc. No.: SDS-ACRN-026

Rev. Number: 1

Rev. Date: Oct 5, 2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Trade name: Custom AccuPlex™ JRCLA**Product Description****Product Code**

Custom AccuPlex™ RNaseP: 10K cps/mL

0505-0372

Custom AccuPlex™ MERS Positive:10k cps/mL

0505-0371

Custom AccuPlex™ Omicron Positive:10k cps/mL

0505-0370

Custom AccuPlex™ Omicron Positive:1k cps/mL

0505-0369

REACH Registration number: Not relevant

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

Product category: Controls (for In Vitro Diagnostics Use) and Reference materials/Panels (Research Use Only)

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

LGC Clinical Diagnostics, Inc

37 Birch Street

Milford, MA 01757

Phone #: (508) 244-6400

US Toll Free: (800) 676-1881

Fax #: (508) 634-3394

www.seracare.com

Email: CDx-CustomerService@LGCGroup.com

EU Authorized Representative:

MediMark Europe Sarl.

11 rue Emile Zola. BP 2332

38033 Grenoble cedex 2 – France

Phone #: +33 (0)4 76 86 43 22

Fax #: +33 (0)4 76 17 19 82

info@medimark-europe.com

1.4 Emergency telephone number:

For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident

Call CHEMTREC Day or Night

Within USA and Canada: 1-800-424-9300 or +1 703-527-3887 (collect calls accepted)

Account number: CCN12505

AUSTRALIA – POISONS INFORMATION CENTER Telephone: 13 11 26

CANADIAN TRANSPORT EMERGENCY CENTER Telephone: (1) 613 996 6666

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 and GHS classification (29 CFR 1910 HCS)

The product is not classified, according to the CLP Regulation.

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS): The product contains no substances which at their given concentration, are considered to be hazardous to health or the environment.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Not applicable

Hazard pictograms: Not applicable

Signal word: Not applicable

Hazard statements: Not applicable

Additional information:

This value refers to knowledge of known, established toxicological or ecotoxicological values.

0 % of the mixture consists of component(s) of unknown toxicity.

Contains 0 % of components with unknown hazards to the aquatic environment.

2.3 Other hazards: Potentially Biohazardous material: This material has the potential to transmit infectious agents and should be handled according to Biosafety recommendations of the United States Center for Disease Control (HHS Publ. No. (CDC) 300859 revised June 2020.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures – Chemical characterization:

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components: The product does not contain reportable quantities of dangerous components.

Composition:			
CAS No.	Components	Classification	% Weight
7732-18-5	Water	N/A	81.79%
56-81-5	Glycerin	Skin Irrit 2; H315 Eye Irrit 2; H319	15%
1405-41-0	Gentamicin sulfate	Acute Tox 4; H302 Skin Irrit 2; H315 Eye Irrit 2; H319	0.05%
26628-22-8	Sodium Azide	Acute Tox. 2; H300 Acute Tox. 1; H310 STOT RE 2; H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 EUH032	0.05%

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Composition:			
CAS No.	Components	Classification	% Weight
77-86-1	TRIS	Eye Irrit 2; H319 Skin Irrit 2; H315	<1%
60-00-4	EDTA	Eye Irrit 2; H319	<0.1%
N/A	Inactivated virus	N/A	<0.01%
N/A	Seracon	N/A	2%

Additional information: For the wording of the listed hazard phrases, refer to section 15.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Remove contaminated clothing and was before reuse. If symptoms persist, call a physician.

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

After eye contact: Remove contact lenses. Protect unharmed eye. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician in case of complaint.

After swallowing: If accidentally swallowed obtain immediate medical attention. Rinse mouth with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

5.2 Suitable extinguishing agents: CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

For safety reasons unsuitable extinguishing agents: No further relevant information.

5.3 Special hazards arising from the substance or mixture: In case of fire, the following can be released: Carbon oxides (CO_x), nitrogen oxides (NO_x), sulphur oxides (SO_x).

5.4 Advice for firefighters Use fire extinguishing methods suitable to surrounding conditions.

Protective equipment: As in any fire, wear self-contained breathing apparatus pressure-demand and full protective gear to prevent contact with skin and eyes.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid breathing vapors, mist or gas. Use personal protective equipment.

6.2 Environmental precautions:

Prevent entry to sewers and public waters.

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6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Keep in suitable, closed containers for disposal. Swab down area with Chlorox or other disinfecting agent.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

This product should be handled as a potentially infectious material, as no known test method procedure can offer complete assurance that products derived from materials of human origin will not transmit infectious agents. Refer to Directive 2000/54/EC or Biosafety recommendations of the United States Center for Disease Control (HHS Publ. No. (CDC) 300859 revised June 2020 for information on handling biohazardous materials.

Avoid contact with the eyes, skin and mucous membranes.

Keep out of the reach of children.

Wear appropriate PPE. Refer to section 8.

Information about fire and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Store as labeled at -20°C or lower until use. Store in a dry, cool and well-ventilated place. Keep container tightly closed when not in use.

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: None.

7.3 Specific end use(s)

See section 1.2

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling biological materials. Wash hands before breaks and at the end of work. Do not eat, drink or smoke during use. Emergency eye wash stations and safety showers should be available in the immediate vicinity of any potential exposure.

Clean work areas with hypochlorite or other disinfecting agent.

Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.

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Protection of hands

:



Protective gloves

Material of gloves

:

The selection of the suitable gloves depends on the material, and marks of quality, and varies from manufacturer to manufacturer.

Penetration time of glove material

:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection

:



Goggles recommended during use

Body protection

:



Protective work clothing

8.3 Environmental exposure controls: None

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:	: Pale yellow to clear liquid
Form	: Liquid
Colour	: Not available
Odour	: Not available
pH value @ 20 °C	: Not available
Change in condition:	:
Melting point/freezing point	: Not determined
Flash point	: Not applicable
Flammability (solid, gas)	: Not applicable
Ignition temperature	: Not applicable
Decomposition temperature	: Not determined
Auto-ignition temperature	: Product is not self-igniting
Explosive properties	: Product does not present an explosion hazard
Explosion limits	:
Lower	: Not determined
Upper	: Not determined
Vapour pressure	: Not determined
Density @ 20 °C	: Not determined

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Relative density	:	Not determined
Vapour density	:	Not determined
Evaporation rate	:	Not determined
Solubility in / Miscibility with water	:	Fully miscible
Partition coefficient: n-octanol/water	:	Not determined
Viscosity	:	
Dynamic	:	Not determined
Kinematic	:	Not determined
Solvent content	:	
VOC content	:	0.00 %
VOC (EC)	:	0.00 %
Solids content	:	0.0 %

9.2 Other information

No further relevant information available.

SECTION 10: Stability and reactivity**10.1 Reactivity:** No further relevant information available.**10.2 Chemical stability:** Product is stable under recommended storage conditions.**Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.**10.3 Possibility of hazardous reactions:** No dangerous reactions known.**10.4 Conditions to avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.**10.5 Incompatible materials:** Strong oxidizing agents, acids and bases.**10.6 Hazardous decomposition products:**Carbon Monoxide, Carbon Dioxide, Nitrogen Oxides, Sulphur Oxides, Hydrogen Chloride gas
No decomposition if stored and applied as directed.**SECTION 11: Toxicological information****11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute toxicity:** Based on available data, the classification criteria are not met.**Skin corrosion/irritation:** Based on available data; the classification criteria are not met.**Serious eye damage/irritation:** Based on available data, the classification criteria are not met.**Respiratory or skin sensitization:** Based on available data, the classification criteria are not met.**Germ cell mutagenicity:** Based on available data, the classification criteria are not met.**Carcinogenicity:** Based on available data, the classification criteria are not met.**Reproductive toxicity:** Based on available data, the classification criteria are not met.**STOT (Specific target organ toxicity)-single exposure:**

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

STOT (Specific target organ toxicity)-repeated exposure:

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

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

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No endocrine disrupting properties anticipated.

11.2.2. Other information

Not applicable

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability: Not applicable

12.3 Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

Additional ecological information:

General notes: Generally not hazardous for water.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable

vPvB: Not applicable

12.6 Endocrine disrupting properties

Does not contain substances with identified endocrine disrupting properties.

12.7 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation:

Dispose and treat as biohazardous waste. Observe all federal, state and local environmental regulations when disposing of this material.

Uncleaned packaging: Avoid contact with skin and clothing. Dispose of in compliance with the respective national and local regulations.

Recommendation: Unused portions and product evaluated using this reagent are to be disposed of as biohazardous waste and incinerated.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

14.1 UN-Number

ADR/ADN, IMDG, IATA

Non-Regulated Material

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14.2	UN proper shipping name	
	ADR/ADN, IMDG, IATA	Non-Regulated Material
14.3	Transport hazard class(es)	
	ADR/ADN, ADN, IMDG, IATA	
	Class	Non-Regulated Material. Not classified as dangerous goods.
14.4	Packing group	
	ADR/ADN, IMDG, IATA	Non-Regulated Material
14.5	Environmental hazards:	Not applicable
14.6	Special precautions for user:	Not applicable
14.7	Transport in bulk according to Annex II of Marpol and the IBC Code:	Not applicable
	UN "Model Regulation":	Non-Regulated Material

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- DIRECTIVE 2012/18/EU on the control of major accidents**
- Named dangerous substances - Annex I** None of the ingredients are listed.
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
- None of the ingredients are listed.
- REGULATION (EU) 2019/1148 on Explosives Precursors**
- Annex I - Restricted Explosives Precursors (Upper limit value for the purpose of licensing under Article 5(3))**
- None of the ingredients are listed.
- Annex II - Reportable Explosives Precursors**
- None of the ingredients are listed.
- REGULATION (EC) No 273/2004 on drug precursors**
- None of the ingredients are listed.
- REGULATION (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
- None of the ingredients are listed.
- National regulations:**
- US Federal Regulations**
- Listed on the US TSCA inventory
- CERCLA Reportable Quantity**
- Listed substances in the product are at low enough levels to not be expected to exceed the RQ
- SARA Section 302**
- This material does not contain any components with a section 302 EHS TPQ.

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SARA 311/312

No SARA Hazards

SARA 313

This product does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

State Regulations**California Proposition 65:**

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

State Right to Know Act

Massachusetts:	None of the components are listed
New Jersey:	None of the components are listed
Pennsylvania:	None of the components are listed
New York:	None of the components are listed
Rhode Island:	None of the components are listed

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

Abbreviations and acronyms:

ADR: Agreement concerning the International Carriage of Dangerous Goods by Road

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

SECTION 16: Other Information

The above information is believed to be accurate, complete and current but does not purport to be all inclusive and shall be used as a guide. LGC Clinical Diagnostics makes no representation or warranties with respect to the product described herein, including but not limited to any implied warranties or merchantability or fitness for a particular use. LGC Clinical Diagnostics assumes no liability or responsibility and authorizes no other person to assume any additional liability or responsibility as a result of the use of this product or the information contained in the Safety Data Sheet.

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