

Safety Data Sheet

AccuPlex™ Non-Respiratory Virus Materials

Doc. No.: SDS-ACRN-22

Rev. Number: 1

Rev. Date: Feb 27, 2023

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

1.1 Product Identifier

Trade name: AccuPlex™

Product Description

AccuPlex™ Monkeypox Positive Reference Material Kit

Product Code

0505-0347

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

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.

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2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008** Non-Regulated Material**Hazard pictograms:** Non-Regulated Material**Signal word:** Non-Regulated Material**Hazard statements:** Non-Regulated Material**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.

Composition:		
CAS No.	Components	% Weight
7732-18-5	Water	82.9%
56-81-5	Glycerin	15%
77-86-1	TRIS	<1.0%
60-00-4	Ethylenediaminetetraacetic Acid (EDTA)	<1.0%
1405-41-0	Gentamicin Sulfate	0.05%
26628-22-8	Sodium Azide	0.05%
N/A	Replication deficient recombinant virus	< 0.01%
N/A	SeraCon II	< 2 %
Hazard Information:		
TRIS CAS No. 77-86-1 EC / List no. 201-064-4	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE3, H335  GHS07: Warning	
EDTA CAS No. 60-00-4 EC List No. 200-449-4 Index No. 607-429-00-8	Eye Irrit. 2A, H319 Acute Tox. 4, H332 Aquatic Chronic, 3, H412  GHS07: Warning	

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Composition:		
CAS No.	Components	% Weight
Gentamycin Sulfate CAS No. 1405-41-0 EC / List No. 215-778-9	Reps. Sens. 1, H334 Skin Sens. 1, H317  GHS08: Danger	
Sodium Azide CAS No. 26628-22-8 EC / List no. 247-852-1 Index number: 011-004-00-7	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Danger  GHS09: Environment  GH06: Acute Toxicity	

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: Composition/information on ingredients

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: Generally, the product does not irritate the skin. If skin irritation occurs, consult a doctor.

After eye contact: If eye irritation occurs, consult a doctor.

Rinse opened eye for several minutes under running water.

After swallowing: If swallowed and symptoms occur, consult a doctor.

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

Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.

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

5.2 Special hazards arising from the substance or mixture: No further relevant information available.

5.3 Advice for firefighters

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. Avoid prolonged contact with eyes, skin, and clothing.

6.2 Environmental precautions: Prevent entry to sewers and public waters.**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.

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 Handle as potentially infectious:** No special precautions are necessary if used correctly. 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 at 2 – 8 °C. Store in a dry, cool and well-ventilated place. Keep container tightly closed when not in use. Keep / store away from direct sunlight, extremely high or low temperatures and incompatible materials.

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**

Additional information about design of technical facilities: No further data; see item 7.

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists valid during the making were used as basis.

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.

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:	:	
Form	:	Liquid Slightly cloudy
Colour	:	Colorless
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

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Density @ 20 °C	:	Not determined
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 % 0.0 g/l / 0.00 lb/gal
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 oxides, Nitrogen Oxides, No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

LD50/LC50 values relevant for classification:

Glycerin (56-81-5)

LD50 Oral Rat: 23000 mg/kg

LD50 Dermal Rabbit: >10 g/kg

LC50 Inhalation: >570 mg/m³

Gentamicin, sulfate salt (1405-41-0)

LD50 Oral Rat: >5 g/kg

TRIS (77-86-1)

LD50 Oral Rat: >5000 mg/kg

LD50 Dermal Rabbit: >5000 g/kg

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Sodium Azide (26628-22-8)
LD50 Oral Rat (26628-22-8) 27 mg/kg
Ethylenediaminetetraacetic acid (60-00-4)
LD50 Oral Rat:>2000 mg/Kg

Primary irritant effect:

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.

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

Additional toxicological information:**CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):**

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:

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

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

SECTION 12: Ecological information**12.1 Toxicity**

Aquatic toxicity: No further relevant information available.

Glycerin (56-81-5)

LC50 Fish1

540000 (51000-57000) mg/l (Exposure time: 96h – Species: Oncorhynchus mykiss (static))

Sodium azide (2668-22-8)

LC50 Fish 1: 0.8 mg/L (Exposure time: 96h – Species: Oncorhynchus mykiss)

LC50 Fish 2: 0.7 mg/L (Exposure time: 96h – Species: Lepomis macrochirus) ErC50 (algae)

0.348 mg/l Ethylenediaminetetraacetic acid (60-00-4)

LC50 fish 1:

34 – 62 mg/l (Exposure time: 96h – Species: Lepomis macrochirus)

EC50 Daphnia 1113 mg/l (Exposure time: 48h – Species Daphnia magna (static))

LC50 fish 2:

44.2 – 76.5 mg/l (Exposure time: 96h – Species: Pimephales promelas (static))

NOEC chronic fish ≥ 25.7 mg/l (Duration: 35d – Species: Brachydanio rerio (Flow-through))

NOEC chronic crustacea 25 mg/l (Duration: 21d – Species: Daphnia magna (Semi-static))

12.2 Persistence and degradability: No further relevant information available.

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.

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12.5 Results of PBT and vPvB assessment**PBT:** Not applicable**vPvB:** Not applicable**12.6 Other adverse effects** No further relevant information available.**SECTION 13: Disposal considerations****13.1 Waste treatment methods****Recommendation:**

Decontamination of excess material using a 10% solution of bleach is recommended. 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

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 Substance is not listed.

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

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

Glycerin (56-81-5)

Listed on the US TSCA inventory

EPA TSCA Regulatory Flag

Y2 – Y2 - indicates an exempt polymer that is a polyester and is made only from reactants included in a specified list of low concern reactants that comprises one of the eligibility criteria for the exemption rule.

TRIS (77-86-1)

Listed on the US TSCA inventory

Ethylenediaminetetraacetic acid (60-00-4)

Listed on the US TSCA inventory

Sodium azide (26628-22-8)

Listed on the US TSCA inventory

Listed on US SARA 302

Subject to report requirements of US SARA 313

SARA Section 302 Threshold Planning Quantity

500 (this material is reactive solid. (The TPQ does not default to 10000 pounds for non-powder, non-molten, non-solution form)

SARA 313 Emission Reporting

1%

State Regulations

Sodium azide (26628-22-8)

US – Massachusetts – Right To Know list

US – New Jersey - Right To Know Hazardous Substance List

US Pennsylvania - Right To Know Environmental Hazard List

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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

Chemical Name:	Glycerin	Sodium azide	Ethylenediaminetetraacetic acid
Massachusetts:	Listed	Listed	Listed
New Jersey:	RTK Haz. Substance List	RTK Haz. Substance List	RTK Haz. Substance List
Pennsylvania:	Not Listed	RTK Enviro. List	RTK Environ. List
Pennsylvania:	Not Listed	Right To Know list	Right To Know list
New York:	Not Listed	Not Listed	Not listed
Rhode Island:	Not Listed	Not Listed	Not listed

International Inventories

Chemical Name:	Glycerin	Sodium azide	Ethylenediaminetetraacetic acid
TSCA:	Listed	Listed	Listed
DSL:	Listed	Listed	Listed
NDSL:	Not Listed	Not Available	Not Listed
EINECS:	Listed	Listed	Listed
CHINA:	Listed	Listed	Listed
KECL:	Listed	Listed	Listed
JAPAN:	Listed	Listed	Listed
AICS:	Listed	Listed	Listed

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases:

H300 Fatal if swallowed

H315 Causes skin irritation

H317 May cause an allergic skin reaction

H319 Causes serious eye irritation

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

H332 Harmful if inhaled.

H335 May cause respiratory irritation

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

H412 Harmful to aquatic life with long lasting effects

EUH032 Contact with acids liberates very toxic gas

EUH210 Safety data sheet available on request

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International

Carriage of Dangerous Goods by Road)

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

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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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 Acute Tox. 2: Acute toxicity – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Data compared to the previous version altered.

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.

Date of preparation / last revision: Feb 13, 2023 / N/A