

## Safety Data Sheet

according to Regulation (EC) No. 453/2010 and 29 CFR § 1910.1200

Revision date: Oct 1, 2021 Version: 3.0

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

### 1.1. Product identifier

Product form : Human Serum
Name : Control – GC3ab L5-L6

Product code : 92-001002

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

#### 1.2.1. Relevant identified uses

Use of the substance/preparation : This product is intended for use as an unassayed internal quality control to monitor the precision

of laboratory testing procedures.

#### 1.2.2. Uses advised against

No additional information available

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

LGC Clinical Diagnostics, Inc.

221 US Route 1

Cumberland Foreside, ME 04110 - USA

800-377-9684; 207-892-1300 Hours: 8:30 AM to 5:00 PM, Eastern Time, Monday through Thursday. 8:30 AM to 4:00 PM on Friday.

#### 1.4. Emergency telephone number

Emergency number : Contact the CHEMTREC® Emergency Call Center for assistance with transportation or

 $haz ardous\, materials\, emergencies\, (24\, hours/day, 7\, days/week).\ \ Refer to\ LGC\ Clinical$ 

Diagnostics, Inc. customer number 798037.

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

#### **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified.

Full text of H-phrases: see section 16.

### Classification according to Directive 67/548/EEC or 1999/45/EC [DPD]

Not classified.

Full text of R-phrases: see section 16.

## Classification according to 2012 29 CFR § 1910.1200 (OSHA-GHS)

Not classified.

### Classification according to WHMIS (Controlled Products Regulations)

Not classified.

## Adverse physicochemical, human health and environmental effects

None under normal conditions. However, product does contain material of human origin and should be considered potentially infectious.

#### 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) : No symbol required Signal word (CLP) : Not Applicable Hazard statements (CLP) : Not Applicable Precautionary statements (CLP) : Not Applicable EUH phrases : Not Applicable

#### Labelling according to 2012 29 CFR § 1910.1200 [OSHA]

Hazard pictograms (OSHA) : No symbol required Signal word (OSHA) : Not Applicable Hazard statements (OSHA) : Not Applicable Precautionary statements (OSHA) : Not Applicable

### 2.3. Other hazards

Each human donor used in the preparation of the product was tested and found non-reactive for Anti-HIV I/II, Anti-HCV, and HbsAg, with kits approved by the United States FDA.

PBT: not relevant – no registration required vPvB: not relevant – no registration required

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### **SECTION 3: Composition/information on ingredients**

#### **Substances**

Not applicable

3.2. **Mixtures** 

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Human Serum Albumin	(CAS No.) 70024-90-7 EINECS:274-272-6	60-100		

Additional information: Contains human sourced and/or potentially infectious material.

Full text of R-, H- and EUH-phrases: see section 16.

#### **SECTION 4: First aid measures**

#### **Description of first aid measures**

First-aid measures after inhalation If symptoms are experienced remove source of contamination or move victim to fresh air. Obtain

medical advice.

First-aid measures after skin contact No health effects expected. If irritation does occur, flush with lukewarm, gently flowing water for

5 minutes or until chemical is removed.

First-aid measures after eye contact No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently

flowing water for 5 minutes or until the chemical is removed. If irritation persists, obtain medical

First-aid measures after in gestion If irritation or discomfort occurs, obtain medical advice immediately.

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

Symptoms/injuries after inhalation Overexposure to mists or spray may produce slight irritation of the respiratory system.

Symptoms/injuries after skin contact May cause slight irritation to the skin. Symptoms/injuries after eye contact May cause slightirritation to eyes. Symptoms/injuries after in gestion May cause gastric irritation.

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

Treat symptomatically.

## **SECTION 5: Firefighting measures**

#### Extinguishing media

Suitable extinguishing media: Powder, alcohol-resistant foam, water spray, carbon dioxide.

Un suitable extinguishing media None known.

#### 5.2 Special hazards arising from the substance or mixture

Fire hazard No particular fire or explosion hazard. In case of fire it can release carbon oxides, nitrogen

oxides, hydrogen chloride and/or chlorine gases, disodium oxide and other toxic and irritating

Reactivity : No dangerous reactions known under normal conditions of use.

Advice for firefighters

Protective equipment for firefighters In case of fire: Wear self-contained breathing apparatus. Wear recommended personal

protective equipment.

#### **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel 6.1.1.

: Wear suitable protective clothing, gloves and eye/face protection. Protective equipment

6.1.2. For emergency responders

**Protective equipment** : Wear suitable protective clothing, gloves and eve/face protection.

Avoid all eve and skin contact and do not breathe spray and mist. Prevent product from entering **Emergency procedures** 

drains.

### **Environmental precautions**

### Prevent product from entering drains.

## Methods and material for containment and cleaning up

For containment : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding

agents).

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid-or universal binding Methods for cleaning up

agents). Collect all waste in suitable and labelled containers and dispose according to local legislation.

### Reference to other sections

### Refer to sections 8 and 13

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### **SECTION 7: Handling and storage**

### Precautions for safe handling

Precautions for safe handling : Avoid all unnecessary exposure. Handle as if potentially infectious.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing

must not be allowed out of the workplace.

#### Conditions for safe storage, including any incompatibilities

Technical measures: Provide local exhaust or general room ventilation.

Keep container tightly closed and dry. Store in well ventilated area. Keep cool. Storage condition(s)

In compatible materials None Known

#### Specific end use(s)

This product is intended for use as an unassayed internal quality control to monitor the precision of laboratory testing procedures.

### SECTION 8: Exposure controls/personal protection

#### 8.1. **Control parameters**

None

#### 8.2. **Exposure controls**

Appropriate engineering controls Either local exhaust or general roomventilation is usually required.

Personal protective equipment Gloves. Safety glasses.





Hand protection If this material may come in contact with the hands during handling and use, we recommend

wearing gloves of the following material(s): natural rubber latex, neoprene, nitrile, or polyvinyl chloride (PVC). Consultyour PPE provider for breakthrough times and the specific glove that is

best for you based on your use patterns.

As a minimum, safety glasses with side shields should be worn when handling this material **Eve** protection

Skin and Body protection If this material may come into contact with the body during handling and use, we recommend

wearing appropriate protective clothing to prevent contact with the skin.

With correct and proper use, and under normal conditions, breathing protection is not required Respiratory protection

Environmental exposure controls None known.

#### **SECTION 9: Physical and chemical properties**

### Information on basic physical and chemical properties

Physical state Liquid

Colour Colourless to slightly yellow

No data available Odour Odour threshold No data available No data available Meltingpoint No data available Solidification point No data available **Boiling point** No data available Flash point No data available Relative evaporation rate (butylacetate=1) No data available Flammability (solid, gas) Not applicable. **Explosive limits** No data available Vapour pressure No data available No data available Relative vapour density at 20 °C Relative density No data available Water: Soluble in water

Solubility Log Pow No data available Log Kow No data available No data available Self ignition temperature No data available Decomposition temperature Viscosity, kinematic No data available Viscosity, dynamic No data available Explosive properties Not explosive. Oxidising properties Not oxidizing.

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Upper flammable Limit : No Data Available
Lower Flammable Limit : No Data Available
Sensitivity to mechanical impact : No Data Available
Sensitivity to static discharge : No Data Available

### **SECTION 10: Stability and reactivity**

#### 10.1. Reactivity

No dangerous reactions known under normal conditions of use.

#### 10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

#### 10.3. Possibility of hazardous reactions

None under normal conditions.

#### 10.4. Conditions to avoid

Incompatible materials.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

### **SECTION 11: Toxicological information**

### 11.1. Information on toxicological effects

Routes of Entry : Skin, Eyes, Inhalation and Ingestion

Acute toxicity : (Mixture not tested. Based on available data.)

## Human Serum Albumin CAS#70024-90-7

No data available

Skin corrosion/irritation : Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Serious eye damage/irritation : Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation : May cause an allergic skin reaction (Mixture not tested. Based on available data.)

Germ cell mutagenicity

Carcinogenicity

Not classified (Mixture not tested. Based on available data, the classification criteria are not met) Not classified (Mixture not tested. Based on available data, the classification criteria are not met). No ingredient present at greater than 0.1% is listed in National Toxicology Program (NTP) Report

Reproductive toxicity
Teratogenicity/Embryotoxicity

on Carcinogens (12th Edition), the International Agency for Research on Cancer (IARC) Monographs (Volumes 1–105), or by OSHA.

Not classified (Mixture not tested. Based on available data, the classification criteria are not met)

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Specific target organ toxicity (single exposure) Specific target organ toxicity (repeated exposure) Not classified (Mixture not tested. Based on available data, the classification criteria are not met)

Not classified (Mixture not tested. Based on available data, the classification criteria are not met)

Aspiration hazard
Potential Adverse human health effects and symptoms

: Not classified (Not applicable): May cause slighttemporary irritation.

Toxicologically Synergistic Materials : None known

### **SECTION 12: Ecological information**

#### 12.1. Toxicity

None

#### 12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

None

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

## Control Kit - GC3ab L5-L6

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

#### 12.6. Other adverse effects

No additional information available

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### **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

Waste disposal recommendations

Dispose of this material and its container at hazardous or special waste collection point. Can be deposited in landfills, sent to an incineration or other appropriate means of disposal provided they meet the requirements of local laws. Comply with applicable local, national and international regulation.

## **SECTION 14: Transport information**

Not regulated for transport.

## **SECTION 15: Regulatory information**

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

#### 15.1.1. EU-Regulations

Contains no REACH candidate substance

#### 15.1.2. National regulations

Regional legislation

: Canada: This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the MSDS contains all the information required by the *Controlled Products Regulations*.

CAS#70024-90-7 is not listed on Canada's DSL List or Ingredient Disclosure List

USA: This product has been classified in accordance with the 2012 hazard criteria of the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS) and the SDS contains all the information required by the 29 CFR § 1910.1200.

#### 15.2. Chemical safety assessment

CSA has not been established

Abbreviations and acronyms

### **SECTION 16: Other information**

Sources of Key data

: Data arise from reference works and literature.

: WHMIS - Workplace Hazardous Material Information System

CFR - Code of Federal Regulations

CLP - Classification, Labelling and Packaging

CSA – Chemical Safety Assessment DPD – Dangerous Products Directive

EC - European Community

EC No. - Éuropean Commission number EEC - European Economic Community

EN - European Norm EU- European Union

GHS - Globally Harmonized System

h-hours

H-phrases - Hazard phrases

Log Pow - Log of the Octanol/Water Partition Coefficient

MSDS - Material Safety Data Sheet

No.-Number

OSHA - Occupational Safety and Health Administration PBT - Persistent, Bioaccumulative and Toxic substance

PPE - Personal Protective Equipment

REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals

R-phrases – Risk phrases SDS – Safety Data Sheet

vPvB - Very Persistent and Very Bio accumulative

WHMIS - Workplace Hazardou's Material Information System

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.