AccuTrak™ Calibration Verification Panel

Safety Data Sheet

Prepared in accordance with Regulation (EC) No. 1907/2006 (REACH), as amended by Commission Regulation (EU) 2020/878, and Regulation (EC) No. 1272/2008 (CLP), as amended, and 29 CFR § 1910.1200.
Revision date: Aug 28, 2026

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

1.1. Product identifier

Product form : Mixture
Name : AccuTrak™ Calibration Verification Panel
Product code : 2400-0255

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 : Intended for *in vitro* diagnostic use in the determination of calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems.

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 hazardous 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 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

Contains human-derived materials. 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 using FDA-accepted test methods.

All source materials have been tested using FDA-accepted methods and found non-reactive for specified infectious disease markers. However, no known test method can offer complete assurance that infectious agents are absent. This product should be handled using standard laboratory biosafety practices.

This mixture does not contain substances assessed as PBT or vPvB at concentrations of 0.1% or greater.

This mixture does not contain substances identified as having endocrine disrupting properties for human health or the environment at concentrations of 0.1% or greater.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Human Serum Albumin	(CAS No.) 70024-90-7 EINECS:274-272-6	0.2-15	

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

4.1. 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 advice.

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

4.2. 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 slight irritation to eyes.

Symptoms/injuries after ingestion : May cause gastric irritation.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

Unsuitable 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 fumes.

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

5.3. 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

6.1.1. For non-emergency personnel

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

6.1.2. For emergency responders

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

Emergency procedures : Avoid all eye and skin contact and do not breathe spray and mist. Prevent product from entering drains.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. 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).

Methods for cleaning up : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect all waste in suitable and labelled containers and dispose according to local legislation.

6.4. Reference to other sections

Refer to sections 8 and 13.

SECTION 7: Handling and storage

7.1. 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.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures:	:	Provide local exhaust or general room ventilation.
Storage condition(s)	:	Keep container tightly closed and dry. Store in well ventilated area. Store in accordance with package labeling.
Incompatible materials	:	None Known

7.3. Specific end use(s)

Intended for *in vitro* diagnostic use in the determination of calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

None

8.2. Exposure controls

Appropriate engineering controls	:	Either local exhaust or general room ventilation 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). Consult your PPE provider for breakthrough times and the specific glove that is best for you based on your use patterns.
Eye protection	:	As a minimum, safety glasses with side shields should be worn when handling this material
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.
Respiratory protection	:	With correct and proper use, and under normal conditions, breathing protection is not required
Environmental exposure controls	:	None known.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Liquid
Colour	:	Colourless to slightly yellow
Odour	:	No data available
Odour threshold	:	No data available
pH	:	No data available
Melting point	:	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
Relative vapour density at 20 °C	:	No data available
Relative density	:	No data available
Solubility	:	Water: Soluble in water
Log Pow	:	No data available
Log Kow	:	No data available
Self ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity, kinematic	:	No data available
Viscosity, dynamic	:	No data available
Explosive properties	:	Not explosive.

Oxidising properties	:	Not oxidizing.
Particle characteristics	:	Not applicable (liquid)
Relative density	:	Data not available
Auto-ignition temperature	:	Data not available

9.2. Other information

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
Information with regard to physical hazard classes	:	No additional information available
Other safety characteristics	:	No additional information 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

This product contains sodium azide at concentrations below classification thresholds. Sodium azide may react with copper, brass, lead, and solder in plumbing systems to form potentially explosive metal azides.

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: Also see Sections 3 and 15 for specific chemical hazards present.

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	:	Not classified. Based on available data and concentration of ingredients, the classification criteria are not met.
Germ cell mutagenicity	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Carcinogenicity	:	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 on Carcinogens (12th Edition), the International Agency for Research on Cancer (IARC) Monographs (Volumes 1–105), or by OSHA.
Reproductive toxicity	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Teratogenicity/Embryotoxicity	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Specific target organ toxicity (single exposure)	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Specific target organ toxicity (repeated exposure)	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met)
Aspiration hazard	:	Not classified (Not applicable)
Potential Adverse human health effects and symptoms	:	May cause slight temporary irritation.
Toxicologically Synergistic Materials	:	None known
Endocrine-disrupting properties	:	Based on available information, this mixture does not contain substances identified as endocrine disruptors for human health in accordance with Commission Delegated Regulation (EU) 2023/707 at concentrations requiring disclosure.

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

AccuTrak™ Calibration Verification Panel
PBT: not relevant – no registration required
vPvB: not relevant – no registration required

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of this material and its container at a hazardous or special waste collection point. Can be deposited in landfills, sent to an incineration facility, or disposed of by other approved methods that comply with applicable local, national and international regulations.

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

No REACH restricted substances are present. No substances from the ECHA Candidate List of SVHC are present. No substances listed in REACH Annex XIV are present. See Section 3 for any hazardous materials if present.

15.1.2. National regulations

Regional legislation : Canada: This product has been classified in accordance with the Hazardous Products Regulations (HPR) and the SDS contains all information required under WHMIS 2015.

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

SECTION 16: Other information

Sources of Key data : Data arise from reference works and literature.

Abbreviations and acronyms : CFR - Code of Federal Regulations
CLP - Classification, Labelling and Packaging
CSA – Chemical Safety Assessment
DPD – Dangerous Products Directive
EC - European Community
EC No. - European Commission number
EN - European Norm
EU- European Union
EU 2020/878 – Commission Regulation (EU) 2020/878 amending Annex II to REACH
Show more lines
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 Bioaccumulative
WHMIS – Workplace Hazardous 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.