VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

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

Revision date: Apr 19, 2024

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

1.1. Product identifier

Product form	:	Mixture
Name	:	VALIDATE® Calibration Verification Test Kit
Product code	:	301ri, 401ro

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 quantitative determination of linearity, 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

Human source material. Each human donor used in the preparation of the product was tested and found to be non-reactive for HIV-1/2, HBV, and HCV with methods approved by the United States FDA, and/or CE approved methods where applicable.

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name of Component	Product identifier	% in Mixture *(see 2.1 for hazards for mixture)*	Classification of Component according to Regulation (EC) No. 1272/2008 [CLP]
Ethanol	(CAS No.) 64-17-5 (EC no) 200-578-6	0.1-2	Flam. Liq.2 (H225)
Human Serum Albumin	(CAS No.) 70024-90-7 EINECS:274-272-6	0.2-15	

Mixture of chemical and biological substances for in vitro diagnostic use.

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. Keep cool.

Incompatible materials : None Known

7.3. Specific end use(s)

Intended for in vitro diagnostic use in the quantitative determination of linearity, 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

Ethanol (64-17-5)		
Austria	MAK (mg/m³)	1900 mg/m³
Austria	MAK (ppm)	1000 ppm
Austria	MAK Short time value (mg/m³)	3800 mg/m³
Austria	MAK Short time value (ppm)	2000 ppm
Belgium	Limit value (mg/m³)	1907 mg/m³
Belgium	Limit value (ppm)	1000 ppm
France	VLE (mg/m³)	9500 mg/m³
France	VLE (ppm)	5000 ppm
France	VME (mg/m³)	1900 mg/m³
France	VME (ppm)	1000 ppm
Germany	TRGS 900 Occupational exposure limit value (mg/m³)	960 mg/m³
Germany	TRGS 900 Occupational exposure limit value (ppm)	500 ppm
Italy - Portugal - USA ACGIH	ACGIH TWA (mg/m³)	1884 mg/m³
Italy - Portugal - USA ACGIH	ACGIH TWA (ppm)	1000 ppm
Spain	VLA-ED (mg/m³)	1910 mg/m³
Spain	VLA-ED (ppm)	1000 ppm
Switzerland	VLE (mg/m³)	1920 mg/m³
Switzerland	VLE (ppm)	1000 ppm
Switzerland	VME (mg/m³)	960 mg/m³
Switzerland	VME (ppm)	500 ppm
Canada (Québec)	VEMP (mg/m³)	1880 mg/m³
Canada (Québec)	VEMP (ppm)	1000 ppm
Australia	TWA (mg/m³)	1920 mg/m³
Australia	TWA (ppm)	1000 ppm

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.

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

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 below hazard limits (≤0.09%). Sodium azide can react with copper, brass, lead and solder in piping systems to form explosive compounds of lead azide and copper azide.

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	
Ethanol (64-17-5)	
LD50 oral mouse	3450 mg/kg
LD50 dermal rabbit	>15800 mg/kg
LD50 inhalation mouse (4h)	21000 ppm

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	:	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

SECTION 12: Ecological information

12.1. Toxicity

Ethanol (64-17-5)	
LC50 fish (24h)	>100 mg/L *Danio rerio*
EC50 Daphnia (48h)	11853-13248 mg/L *Daphnia magna*

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Ethanol (64-17-5)	
Log P(oct)	= -0.31

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

VALIDATE® Calibration Verification Test Kit
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 in a safe manner in accordance with local/national regulations. Flush pipes with water frequently if discarding solutions containing sodium azide into metal piping systems

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 SDS 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

SECTION 16: Other information

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

Abbreviations and acronyms : 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. - European 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 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.