



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	: 1200ab, 1200au, 1200bc, 1200re, 1200sa, 1200sd

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 <i>in vitro</i> diagnostic use in the determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems.
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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)
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Classification according to 2012 29 CFR § 1910.1200 [OSHA GHS]

Not classified

Classification according to WHMIS (HPR) (SOR/2015-17)

Adverse physicochemical, human health and environmental effects

No hazards expected.

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

None

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

according to Regulation (EC) No. 453/2010, EC 1272/2008, EC 1907/2006, and 29 CFR § 1910.1200

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	0.1-1	Flam. Liq.2 (H225)

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 : Take proper precautions to ensure your own safety before attempting rescue (e.g. wear appropriate protective equipment). Remove source of contamination or move person to fresh air. Consult a physician.
- First-aid measures after skin contact : Avoid direct contact. Wear chemical resistant protective clothing if necessary. As quickly as possible, flush with lukewarm gently flowing water for at least 20 minutes or until the chemical is removed.
- First-aid measures after eye contact : Avoid direct contact. Wear chemical resistant gloves if necessary. Quickly and gently blot away chemical. Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for at least 20 minutes or until the chemical is removed, while holding the eyelid(s) open. Neutral saline solution may be used as soon as it is available. If irritation persists, consult a physician.
- First-aid measures after ingestion : NEVER give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. Have victim rinse mouth thoroughly with water. If irritation persists, obtain medical attention 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 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: : Carbon dioxide, dry chemical powder, appropriate foam, water spray or fog.
- 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 hydrogen gas, chlorine gas and other toxic and irritating fumes. Hazardous decomposition products formed under fire conditions include carbon oxides, nitrogen oxides (NO_x), sulphur oxides and hydrogen chloride gas.
- 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.

VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

according to Regulation (EC) No. 453/2010, EC 1272/2008, EC 1907/2006, and 29 CFR § 1910.1200

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 contact with eyes and skin. 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).

Methods for cleaning up : Absorb with liquid-binding material (e.g. sand, diatomaceous earth). 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.

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 : Strong oxidizing agents, strong reducing agents, strong bases, strong acids, metal nitrates and fluorine.

7.3. Specific end use(s)

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

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Safety Data Sheet

according to Regulation (EC) No. 453/2010, EC 1272/2008, EC 1907/2006, and 29 CFR § 1910.1200

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethanol (64-17-5)		
Austria	MAK (mg/m ³)	1900 mg/m ³
Austria	MAK (ppm)	1000 ppm
Austria	MAK Short time value (mg/m ³)	3800 mg/m ³
Austria	MAK Short time value (ppm)	2000 ppm
Belgium	Limit value (mg/m ³)	1907 mg/m ³
Belgium	Limit value (ppm)	1000 ppm
France	VLE (mg/m ³)	9500 mg/m ³
France	VLE (ppm)	5000 ppm
France	VME (mg/m ³)	1900 mg/m ³
France	VME (ppm)	1000 ppm
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	960 mg/m ³
Germany	TRGS 900 Occupational exposure limit value (ppm)	500 ppm
Italy - Portugal - USA ACGIH	ACGIH TWA (mg/m ³)	1884 mg/m ³
Italy - Portugal - USA ACGIH	ACGIH TWA (ppm)	1000 ppm
Spain	VLA-ED (mg/m ³)	1910 mg/m ³
Spain	VLA-ED (ppm)	1000 ppm
Switzerland	VLE (mg/m ³)	1920 mg/m ³
Switzerland	VLE (ppm)	1000 ppm
Switzerland	VME (mg/m ³)	960 mg/m ³
Switzerland	VME (ppm)	500 ppm
Canada (Québec)	VEMP (mg/m ³)	1880 mg/m ³
Canada (Québec)	VEMP (ppm)	1000 ppm
Australia	TWA (mg/m ³)	1920 mg/m ³
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 consulting 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. If the occupational exposure limit is exceeded: Use multi-purpose combination (US) or type ABEK (EN) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- Environmental exposure controls : None known.

VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

according to Regulation (EC) No. 453/2010, EC 1272/2008, EC 1907/2006, and 29 CFR § 1910.1200

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Clear 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 Section 7.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

Incompatible materials.

10.5. Incompatible materials

Strong oxidizing agents, reducing agents, strong acids, metals, bases and fluorine.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

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Safety Data Sheet

according to Regulation (EC) No. 453/2010, EC 1272/2008, EC 1907/2006, and 29 CFR § 1910.1200

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 : Harmful if swallowed (Mixture not tested. Based on available data on mixture.)

Ethanol (64-17-5)	
LD50 oral mouse	3450 mg/kg
LD50 dermal rabbit	>15800 mg/kg
LC50 inhalation mouse (4h)	21000 ppm

Skin corrosion/irritation : Not classified under GHS criteria. (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 (Mixture not tested. Based on available data, 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 : Not classified (Mixture not tested. Based on available data, the classification criteria are not met)

SECTION 12: Ecological information

12.1. Toxicity

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

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

VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

according to Regulation (EC) No. 453/2010, EC 1272/2008, EC 1907/2006, and 29 CFR § 1910.1200

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 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

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 hazard criteria of the according to WHMIS Hazardous Products Regulations (HPR) (SOR/2015-17)

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

VALIDATE® Calibration Verification Test Kit

Safety Data Sheet

according to Regulation (EC) No. 453/2010, EC 1272/2008, EC 1907/2006, and 29 CFR § 1910.1200

SECTION 16: Other information

Sources of Key data	: Data arise from reference works and literature.
Abbreviations and acronyms	: ACGIH - American Conference of Governmental Industrial Hygienists CAS No. - Chemical Abstracts Service number CEN - Comité Européen de Normalisation 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 EC50 - Effective Concentration - 50% EEC - European Economic Community EN- European Norm EU- European Union GHS - Globally Harmonized System h - hours H-phrases - Hazard phrases LC50 - Lethal Concentration - 50% LD50 - Lethal Dose - 50% Log Pow - Log of the Octanol/Water Partition Coefficient MAK - Maximale Arbeitsplatz-Konzentration MSDS - Material Safety Data Sheet NIOSH - National Institute for Occupational Safety and Health 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 STEL- Short-Term Exposure Limit TWA- Time-Weighted Average US - United States (of America) USA- United States (of America) VEMP - Valeur d'Exposition Moyenne Pondérée VLA-ED - Valor Límite Ambiental de Exposición Diaria VLE - Valeur Limite d'Exposition VME - Valeur Limite de Moyenne d'Exposition Professionnelle vPvB - Very Persistent and Very Bioaccumulative WHMIS - Workplace Hazardous Material Information System

Full text of R-, H- and EUH-phrases:

Skin Sens. 1	Skin Sensitisation Category 1
Xn	Harmful
Xi	Irritant
H225	Highly flammable liquid and vapour
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
R10	Flammable
R22	Harmful if swallowed
R43	May cause sensitisation by skin contact

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.