VALIDATE® Calibration Verification Test Kits

Safety Data Sheet

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

Revision date: Apr 1, 2025 Version: 11.0

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 : 704ab, 704au, 704bc, 704db, 704ri, 704sa

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

This material is considered hazardous according to Regulation (EC) No. 1272/2008 [CLP]

This material is considered hazardous according to 2012 29 CFR § 1910.1200 [OSHA GHS]

Hazardous

This material is considered hazardous according to WHMIS Hazardous Products Regulations (HPR) (SOR/2015-17))

Skin corrosion (Category 1B), H314

Serious eye damage (Category 1), H318

Adverse physicochemical, human health and environmental effects

This product contains Hydrochloric acid which is corrosive to eyes and skin. Harmful if inhaled. Harmful if swallowed.

2.2. Label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : Skin corr. 1, Causes severe skin burns and eye damage (H314)

Serious eye damage 1, Causes serious eye damage (H318)

Precautionary statements : P280 Wear protective gloves/protective clothing/eye protection/face protection

2.3. Other hazards

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)*	Hazard Classes and Hazard Categories
Hydrochloric acid	(CAS No.) 7647-01-0 (EC no) 231-595-7	1-5	Met. Corr. 1 H290 Eye Dam. 1 H318 Skin Corr. 1B H314 STOT SE 3 H335 M-Factors: Skin Irrit. 2; H315: 10% ≤ C < 25% Eye Irrit. 2; H319: 10% ≤ C < 25% STOT SE 3; H335: C ≥ 10% Skin Corr. 1B; H314: C ≥ 25%

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 victim to fresh air.

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 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 20 minutes or until the chemical is removed, while holding the eyelid(s) open. Take care not to rinse contaminated water into the unaffected eye or onto the face. Obtain medical attention immediately.

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. DO NOT INDUCE VOMITING. Have victim drink 240 to 300 ml (8 to 10 oz.) of water to dilute material in stomach. If milk is available, it may be administered AFTER the water has been given. If vomiting occurs naturally, have victim lean forward to reduce risk of aspiration. Repeat administration of water. Quickly transport victim to an emergency care facility.

4.2. Most important symptoms and effects, both acute and delayed

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

Symptoms/injuries after skin contact : Moderately irritating to skin.

Symptoms/injuries after eye contact : Moderately irritating to eyes.

Symptoms/injuries after ingestion : Harmful if swallowed.

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 and 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 hydrogen gas, chlorine gas 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).

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 : Oxidizing agents, reducing agents, metals, bases, sulfuric acid and perchloric acid.

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

Hydrochloric acid (7647-01-0)		
Austria	Occupational Exposure Level (OEL) -STELs - (MAKKZWs)	10 ppm STEL [KZW]; 15 mg/m³ STEL [KZW]
Austria	OEL-TWAs - (MAKTMWs)	5 ppm TWA [TMW]; 8 mg/m³ TWA [TMW]
Belgium	OEL -STELs	10 ppm STEL; 15 mg/m³ STEL
Belgium	OEL -TWAs	5 ppm TWA; 8 mg/m³ TWA
Bulgaria	OEL -STELs	15.0 mg/m³ STEL
Bulgaria	OEL -TWAs	8.0 mg/m³ TWA
Cyprus	OEL -STELs	10 ppm STEL; 15 mg/m³ STEL
Cyprus	OEL -TWAs	5 ppm TWA; 8 mg/m³ TWA
Czech Republic	OEL -Ceilings	15 mg/m³ Ceiling
Czech Republic	OEL -TWAs	8 mg/m³ TWA
Denmark	OEL -Ceilings	5 ppm Ceiling; 8 mg/m³ Ceiling
Estonia	OEL -STELs	10 ppm STEL; 15 mg/m³ STEL
Estonia	OEL -TWAs	5 ppm TWA; 8 mg/m³ TWA
Finland	OEL -STELs	5 ppm STEL (including solution); 7.6 mg/m³ STEL (including solution)
France	OEL –STELs (VLCT)	5 ppm STEL [VLCT] (restrictive limit); 7.6 mg/m³ STEL [VLCT] (restrictive limit)

Hydrochloric acid (7647-01-0)		
Germany	DFG –Recommended Exposure Limits - Ceilings (Peak Limitations)	4 ppm Peak; 6 mg/m³ Peak
Germany	DFG – Recommended Exposure Limits -TWAs (MAKs)	2 ppm TWA MAK; 3.0 mg/m³ TWA MAK
Greece	OEL -STELs	5 ppm STEL; 7 mg/m³ STEL
Greece	OEL -TWAs	5 ppm TWA; 7 mg/m³ TWA
Hungary	OEL –STELs (CKs)	16 mg/m³ STEL [CK]
Hungary	OEL –TWAs (AKs)	8 mg/m³ TWA [AK]
Ireland	OEL -STELs	10 ppm STEL; 15 mg/m³ STEL
Ireland	OEL -TWAs	5 ppm TWA; 8 mg/m³ TWA
Italy	OEL -STELs	10 ppm STEL; 15 mg/m³ STEL
Italy	OEL -TWAs	5 ppm TWA; 8 mg/m³ TWA
Italy	Recommended Exposure Limits Based on ACGIH TLVs - Ceilings	2 ppm Ceiling
Latvia	OEL -STELs	10 ppm STEL; 15 mg/m³ STEL
Latvia	OEL -TWAs	5 ppm TWA; 8 mg/m³ TWA
Lithuania	OEL - STELs (TPRDs)	10 ppm STEL [TPRD]; 15 mg/m³ STEL [TPRD]
Lithuania	OEL -TWAs (IPRDs)	5 ppm TWA [IPRD]; 8 mg/m³ TWA [IPRD]
Luxembourg	OEL -STELs	10 ppm STEL; 15 mg/m³ STEL
Luxembourg	OEL -TWAs	5 ppm TWA; 8 mg/m³ TWA
Malta	OEL -STELs	10 ppm STEL; 15 mg/m³ STEL
Malta	OEL -TWAs	5 ppm TWA; 8 mg/m³ TWA
Netherlands	OEL -STELs	15 mg/m³ STEL
Netherlands	OEL -TWAs	8 mg/m³ TWA
NIOSH	Pocket Guide – Ceiling Limits	5 ppm Ceiling; 7 mg/m³ Ceiling
NIOSH	NIOSH – Pocket Guide – IDLHs (Immediately Dangerous to Life or Health)	50 ppm IDLH
OSHA	Permissible Exposure Limits (PELs)	Ceiling Exposure Limit (PEL-C): 5 ppm (7 mg/m³)
Poland	OEL -STELs (NDSChs)	10 mg/m³ STEL [NDSCh]
Poland	OEL -TWAs (NDSs)	5 mg/m³ TWA [NDS]
Portugal	OEL- Ceilings (VLE-CMs)	2 ppm Ceiling [VLE-CM]
Romania	OEL -STELs	10 ppm STEL; 15 mg/m³ STEL
Romania	OEL -TWAs	5 ppm TWA; 8 mg/m³ TWA
Slovak Republic	OEL -Ceilings	15 mg/m³ Ceiling
Slovak Republic	OEL -TWAs	5 ppm TWA; 8.0 mg/m³ TWA
Slovenia	OEL -STELs	10 ppm STEL (anhydrous); 16 mg/m³ STEL (anhydrous)
Slovenia	OEL -TWAs	5 ppm TWA (anhydrous); 8 mg/m³ TWA (anhydrous)
Spain	OEL-STELs (VLA-ECs)	10 ppm STEL [VLA-EC]; 15 mg/m³ STEL [VLAEC]
Spain	OEL-TWAs (VLA-EDs)	5 ppm TWA [VLA-ED] (indicative limit value); 7.6 mg/m³ TWA [VLA-ED] (indicative limit value)
Sweden	OEL-Ceilings (CLVs)	5 ppm CLV; 8 mg/m³ CLV
Switzerland	OEL-STELs - (KZWs)	4 ppm STEL [KZW]; 6 mg/m³ STEL [KZW]
Switzerland	OEL-TWAs - (MAKs)	2 ppm TWA [MAK]; 3.0 mg/m³ TWA [MAK]
United Kingdom	Workplace Exposure Limits (WELs) - STELs	5 ppm STEL (aerosol mist and gas); 8 mg/m³ STEL (aerosol mist and gas)
United Kingdom	WELs - TWAs	1 ppm TWA (aerosol mist and gas); 2 mg/m³ TWA (aerosol mist and gas)

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, 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. 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.

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 Section 7.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

Incompatible materials

10.5. Incompatible materials

Oxidizing agents, reducing agents, metals, bases, sulfuric acid and perchloric acid.

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	:	Harmful if swallowed (Mixture not tested. Based on available data on 6.5% of mixture.)

Hydrochloric acid (7647-01-0)	
LD50 oral rat	238-277 mg/kg
LD50 dermal rabbit	>5010 mg/kg
LC50 inhalation mouse (4h)	554 ppm

Skin corrosion/irritation	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met) This product contains an ingredient at ≥ 1% that meets the WHMIS classification for corrosive material; therefore this untested mixture is considered corrosive under Canadian classification criteria.
Serious eye damage/irritation	:	Not classified (Mixture not tested. Based on available data, the classification criteria are not met) This product contains an ingredient at ≥ 1% that meets the WHMIS classification for corrosive material; therefore this untested mixture is considered corrosive under Canadian classification criteria.
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	:	Harmful if inhaled. Harmful if swallowed.
Toxicologically Synergistic Materials	:	None known

SECTION 12: Ecological information

12.1. Toxicity

Hydrochloric acid (7647-01-0)	
LC_{50} fish (24h, 48h and 96h)	282 mg/L *Gambusia affinis*
LC_{50} fish (96h)	24.6-30.9 mg/L *Lepomis macrochirus*
LC_{50} fish (96h)	7.45 mg/L *Oncorhynchus mykiss*
EC_{50} algae (72hr)	0.0492 mg/L *Selenastum capricornutum (Green algae)*

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Hydrochloric acid (7647-01-0)	
Log P(oct) (36% hydrochloric acid)	= 0.3

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

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 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

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 Hazardous Products Regulations and the SDS contains all the information required by the *Hazardous Products Regulations*.

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

SARA 302

This material does not contain any components with a Section 302 Extremely Hazardous Substance threshold planning quantity.

SARA 311/312

Acute Health Hazard. See Section 2 for more information.

SARA 313

The following components are subject to reporting levels established by SARA Title III, Section 313

Hydrochloric Acid (Aerosol forms only) CAS-No. 7647-01-0

CERCLA

Hydrochloric Acid CAS-No. 7647-01-0 Reportable Quantity 5000 pounds

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 : 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)
VLA-ED - Valor Límite Ambiental de Exposición Diaria
VLE - Valeur Limite d'Exposition
vPvB - Very Persistent and Very Bioaccumulative
WHMIS – Workplace Hazardous Material Information System

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

Acute Tox. 2	Acute Toxicity Category 2
Acute Tox. 4	Acute Toxicity Category 4
Skin Corr. 1B	Skin Corrosion Category 1B
STOT SE 3	Specific Target Organ Toxicity Single Exposure Category 3
Skin Irrit. 2	Skin Irritation Category 2
Eye Irrit. 2	Eye Irritation Category 2
T	Toxic
Xn	Harmful
C	Corrosive
Xi	Irritant
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H319	Causes serious eye irritation
H330	Fatal if inhaled
H302	Harmful if swallowed
H335	May cause respiratory irritation
R23	Toxic by inhalation
R20	Harmful by inhalation
R34	Causes burns
R37	Irritating to respiratory 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.