



VALIDATE® Chem 4 Calibration Verification Test Set

Safety Data Sheet

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

Revision date: Oct 1, 2021

Version: 10.0

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

1.1. Product identifier

Product form : Mixture
Name : VALIDATE® Chem 4 Calibration Verification Test Set
Product code : 104ab

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]

Acute Tox. 4 H302
Repr. 2 H361d

Full text of H-phrases: see section 16.

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

Xn; R22
Repr. Cat. 3; R63

Full text of R-phrases: see section 16.

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

Acute Tox. 4
Repr. 2

Classification according to WHMIS (Controlled Products Regulations)

D2A

Adverse physicochemical, human health and environmental effects

May be slightly irritating to skin and eyes. Harmful if swallowed.

VALIDATE® Chem 4 Calibration Verification Test Set

Safety Data Sheet

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

2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS07



GHS08

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed

H361d - Suspected of damaging the unborn child.

Precautionary statements (CLP)

: P201 - Obtain special instructions before use.

P264 - Wash exposed skin thoroughly after handling.

P281 - Use personal protective equipment as required.

P308 + P313 - IF exposed or concerned: Get medical advice/attention.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local/regional/national/ international regulation.

EUH phrases

: EUH210 - Safety data sheet available on request

Labelling according to 2012 29 CFR § 1910.1200 [OSHA]

Hazard pictograms (OSHA)

:



Signal word (OSHA)

: Warning

Hazard statements (OSHA)

: Harmful if swallowed

Suspected of damaging the unborn child

Precautionary statements (OSHA)

: Do not handle until all safety precautions have been read and understood.

Use personal protective equipment as required.

Wash exposed skin thoroughly after handling.

IF exposed or concerned: Get medical advice/attention.

Do not eat, drink or smoke when using this product.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/ international regulation.

2.3. Other hazards

Animal source of this product meets USDA guidelines. The animals received ante and post mortem health inspection at the abattoir and they were apparently free from infectious and contagious diseases. The BSA product is of US origin and meets the current standards for reduction of TSE (Transmissible Spongiform Encephalopathy) risk.

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	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Bovine Serum Albumin	(CAS No.) 9048-46-8 (EC no) 232-936-2	7-13	N/A	N/A
Ethylene Glycol	(CAS No.) 107-21-1 (EC no) 203-473-3	30-60	Xn; R22 Repr. Cat. 3; R63	Acute Tox. 4 H302 Repr 2 H361d

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

VALIDATE® Chem 4 Calibration Verification Test Set

Safety Data Sheet

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

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 | : Wash skin with plenty of water and soap for 5 minutes. |
| First-aid measures after eye contact | : Rinse cautiously with water for several minutes. |
| First-aid measures after ingestion | : NEVER give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. DO NOT INDUCE VOMITING. Have victim drink 60 to 240 mL (2 to 8 oz.) of water. If vomiting occurs naturally, have victim rinse mouth with water again. Obtain medical advice. |

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 | : 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, 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, formaldehyde, 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

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|----------------------|--|
| 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. |
| 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. |

VALIDATE® Chem 4 Calibration Verification Test Set

Safety Data Sheet

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

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 bases; Perchloric acid; Phosphorus(V) sulfide; Strong acids; Nitrogen compounds; Peroxyacetic acid and acetic acid; Bromine trifluoride; Lithium.

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

Ethylene Glycol (107-21-1)		
Austria	MAK (mg/m ³)	26 mg/m ³
Austria	MAK (ppm)	10 ppm
Austria	MAK Short time value (mg/m ³)	52 mg/m ³
Austria	MAK Short time value (ppm)	20 ppm
Belgium	Limit value (mg/m ³)	52 mg/m ³
Belgium	Limit value (ppm)	20 ppm
Belgium	Limit value Shorttime value (mg/m ³)	104 mg/m ³
Belgium	Limit value Shorttime value (ppm)	40 ppm
France	VLE (mg/m ³)	104 mg/m ³
France	VLE (ppm)	40 ppm
France	VME (mg/m ³)	52 mg/m ³
France	VME (ppm)	20 ppm
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	52 mg/m ³
Germany	TRGS 900 Occupational exposure limit value (ppm)	20 ppm
Italy - Portugal - USA ACGIH	ACGIH TLV-C (mg/m ³)	100 mg/m ³
Spain	VLA-ED (mg/m ³)	52 mg/m ³
Spain	VLA-ED (ppm)	20 ppm
Switzerland	VLE (mg/m ³)	52 mg/m ³
Switzerland	VLE (ppm)	20 ppm
Switzerland	VME (mg/m ³)	26 mg/m ³
Switzerland	VME (ppm)	10 ppm
Canada (Québec)	VEMP (mg/m ³)	127 mg/m ³
Canada (Québec)	VEMP (ppm)	50 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. 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® Chem 4 Calibration Verification Test Set

Safety Data Sheet

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

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

None under normal conditions.

10.4. Conditions to avoid

Incompatible materials.

10.5. Incompatible materials

Strong oxidizing agents; Strong bases; Perchloric acid; Phosphorus(V) sulfide; Strong acids; Nitrogen compounds; Peroxyacetic acid and acetic acid; Bromine trifluoride; Lithium.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

VALIDATE® Chem 4 Calibration Verification Test Set

Safety Data Sheet

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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.)

Bovine Serum Albumin (9048-46-8)	
LD50 oral rat (ATE)	500 mg/kg bw
Ethylene Glycol (107-21-1)	
LD50 oral rat (ATE)	500 mg/kg bw

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 (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	: Contains an ingredient suspected of damaging the unborn child at >0.1%. The mixture is classified as suspected of damaging the unborn child according to Regulation 1272/2008 [CLP], OSHA 29 CFR § 1910.1200 and WHMIS. (Mixture not tested. Based on available data.)
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

Ethylene Glycol (107-21-1)	
LC50 fish (96h)	18500 mg/L <i>Oncorhynchus mykiss</i>

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Ethylene Glycol (107-21-1)	
Log Pow	-1.36

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

VALIDATE® Chem 4 Calibration Verification Test Set	
PBT: not relevant – no registration required	
vPvB: not relevant – no registration required	

12.6. Other adverse effects

No additional information available

VALIDATE® Chem 4 Calibration Verification Test Set

Safety Data Sheet

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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*.

WHMIS Classification:

D2A – Very Toxic Material – Teratogenicity and Embryotoxicity

WHMIS Symbols:



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® Chem 4 Calibration Verification Test Set

Safety Data Sheet

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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 ATE – Acute Toxicity Estimate BSA – Bovine Serum Albumin 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 EEC - European Economic Community EN - European Norm 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 TRGS - Die Technischen Regeln für Gefahrstoffe US – United States (of America) USDA - United States Department of Agriculture 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:

Acute Tox. 4	Acute Toxicity Category 4
Repr. 2	Reproductive toxicity Category 2
Xn	Harmful
Repr. Cat. 3	Toxic For Reproduction Category 3
R22	Harmful if swallowed
R63	Possible risk of harm to the unborn child

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.