



VALIDATE[®] Calibration Verification/Linearity Test Set

Safety Data Sheet

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

Revision date: Nov 6, 2024

Version: 8.0

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

1.1. Product identifier

Product form	: Mixture
Name	: VALIDATE [®] Calibration Verification/Linearity Test Set
Product code	: 1001ro, 1400bc, 1400sa, 1400sd, 1400re, 1400vt, 1400ab

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

Adverse physicochemical, human health and environmental effects

Rapidly absorbed through skin. 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

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

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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]
Dimethyl sulfoxide	(CAS No.) 67-68-5 (EC no) 200-664-3	< 5	N/A
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 : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
- First-aid measures after skin contact : Wash skin with plenty of water and soap.
- First-aid measures after eye contact : Rinse cautiously with water for several minutes.
- First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

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

- Symptoms/injuries after inhalation : Overexposure to mists or vapours 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 : Ingestion of small amounts would not be expected to produce toxicity.

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 (CO and CO2). Sulfur oxides.
- 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 vapour 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.

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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.

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 under inert atmosphere.
- Incompatible materials : Strong acid. Strong oxidizing agents. Strong reducing agents.

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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Dimethyl sulfoxide (67-68-5)		
Austria	MAK (mg/m³)	160 mg/m³
Austria	MAK (ppm)	50 ppm
Switzerland	VLE (mg/m³)	320 mg/m³
Switzerland	VLE (ppm)	100 ppm
Switzerland	VME (mg/m³)	160 mg/m³
Switzerland	VME (ppm)	50 ppm
Denmark	Grænseværdie (langvarig) (mg/m³)	160 mg/m³
Denmark	Grænseværdie (langvarig) (ppm)	50 ppm
Denmark	Grænseværdie (kortvarig) (mg/m³)	320 mg/m³
Denmark	Grænseværdie (kortvarig) (ppm)	100 ppm
Finland	HTP-arvo (8h) (ppm)	50 ppm
Finland	Huomautus (FI)	iho
Lithuania	IPRV (mg/m³)	150 mg/m³
Lithuania	IPRV (ppm)	50 ppm
Lithuania	TPRV (mg/m³)	500 mg/m³
Lithuania	TPRV (ppm)	150 ppm
Lithuania	Remark (LT)	O
Sweden	nivågränsvärde (NVG) (mg/m³)	150 mg/m³
Sweden	nivågränsvärde (NVG) (ppm)	50 ppm
Sweden	kortidsvärde (KTV) (mg/m³)	500 mg/m³
Sweden	kortidsvärde (KTV) (ppm)	150 ppm
Sweden	Anmärkning (SE)	H

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 : In case of repeated or prolonged contact wear gloves.
- Eye protection : Safety glasses.
- 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.

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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	: > 97 °C (Closed cup)
Relative evaporation rate (butylacetate=1)	: No data available
Flammability (solid, gas)	: Not applicable.
Explosive limits	: Not applicable vol %
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

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

Hygroscopic. 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 acid. Strong oxidizing agents. Strong reducing agents.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects: Also see Sections 3 and 15 for specific chemical hazards present.

Acute toxicity : Not classified (Mixture not tested. Based on available data, the classification criteria are not met)

Dimethyl sulfoxide (67-68-5)

LD50 oral rat	14500 mg/kg
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)
Reproductive toxicity	: 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. Prolonged or repeated contact with the skin may cause dermatitis.
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

Dimethyl sulfoxide (67-68-5)

LC50 fishes 1	34 mg/l (Exposure time: 96 h - Species: Pimephales promelas)
EC50 Daphnia 1	7000 mg/l (Exposure time: 24 h - Species: Daphnia species)
EC50 other aquatic organisms 1	12350 - 25500 mg/l (Exposure time: 96 h - Species: Skeletonema costatum)
LC50 fishes 2	33 - 37 g/l (Exposure time: 96 h - Species: Oncorhynchus mykiss)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Dimethyl sulfoxide (67-68-5)

Log Pow	-2.03
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

VALIDATE® GC4 Calibration Verification/Linearity Test Set

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 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 a dangerous good in sense of transport regulations.

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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 : 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 : EC - European Community. CLP - Classification, Labelling and Packaging. EEC - European Economic Community. HCS - Hazard Communication Standard. OSHA - Occupational Safety and Health Administration. CAS (Chemical Abstracts Service) number. REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals. ATE - acute toxicity estimate. BCF - bioconcentration factor. PBT - Persistent, Bioaccumulative and Toxic substance. vPvB - Very Persistent and Very Bioaccumulative.

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

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.