



Alere LDX Calibration Verification and Controls

Safety Data Sheet

according to Regulation (EC) No. 453/2010

Revision: 3

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

1.1. Product identifier

Product form : Substance
 Substance name : Alere LDX Calibration Verification and Controls
 Product code : 88769 88773 88770,
 Product group : Trade product

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : Professional use
 Industrial/Professional use spec : For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Alere San Diego, Inc. d/b/a Biosite Incorporated
 9975 Summers Ridge Road
 92121 San Diego, CA
 T (858) 455-4808 - F (858) 455-4815
david.ivester@alere.com - www.Alere.com

1.4. Emergency telephone number

Emergency number : For Alere Medical Test Device / Test Device Kit information and technical assistance, please contact the Alere Technical Services Department at 1-888-246-7483 (option 2).

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 Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Not classified

2.2. Label elements

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

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Name : Alere LDX Calibration Verification and Controls

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Deionized water	(CAS No) 7732-18-5 (EC-No.) 231-791-2	97.277109 - 97.277112	Not classified
4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid	(CAS No) 7365-45-9 (EC-No.) 230-907-9	1.00462	Not classified
Treated Avian Triglyceride		0.3	Not classified
Aminotransferase, alanine	(CAS No) 9000-86-6 (EC-No.) 232-561-4	0.25	Not classified
glucose, D-	(CAS No) 50-99-7 (EC-No.) 200-075-1	0.23446	Not classified
AST		0.175	Not classified

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Name	Product identifier	%	Classification according to Directive 67/548/EEC
magnesium chloride	(CAS No) 7786-30-3 (EC-No.) 232-094-6	0.15227	Not classified
Human LDL Cholesterol		0.13898	Not classified
Ethylenediamine tetraacetic acid, disodium salt	(CAS No) 6381-92-6 (EC-No.) 205-358-3	0.11873	Not classified
tertiary-octylphenoxypoly(ethoxyethanol)	(CAS No) 9036-19-5	0.08582	Xi; R36/38
Human HDL Cholesterol		0.075	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC-No.) 231-598-3	0.07307	Not classified
METHYLPARABEN	(CAS No) 99-76-3 (EC-No.) 202-785-7	0.03939	Not classified
chloramphenicol	(CAS No) 56-75-7 (EC-No.) 200-287-4	0.01478	Carc.Cat.2; R45 Repr.Cat.3; R63
SUCROSE	(CAS No) 57-50-1 (EC-No.) 200-334-9	0.0136	Not classified
SERUM ALBUMIN	(CAS No) 9048-46-8 (EC-No.) 232-936-2	0.012657	Not classified
2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol	(CAS No) 4719-04-4 (EC-No.) 225-208-0 (EC index no) 613-114-00-6	0.000038 - 0.000041	Xn; R22 R43
Piperacillin			Not classified
Name	Product identifier	Specific concentration limits	
2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol	(CAS No) 4719-04-4 (EC-No.) 225-208-0 (EC index no) 613-114-00-6	(C >= 0.1) R43	
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Deionized water	(CAS No) 7732-18-5 (EC-No.) 231-791-2	97.277109 - 97.277112	Not classified
4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid	(CAS No) 7365-45-9 (EC-No.) 230-907-9	1.00462	Not classified
Treated Avian Triglyceride		0.3	Not classified
Aminotransferase, alanine	(CAS No) 9000-86-6 (EC-No.) 232-561-4	0.25	Not classified
glucose, D-	(CAS No) 50-99-7 (EC-No.) 200-075-1	0.23446	Not classified
AST		0.175	Not classified
magnesium chloride	(CAS No) 7786-30-3 (EC-No.) 232-094-6	0.15227	Not classified
Human LDL Cholesterol		0.13898	Not classified
Ethylenediamine tetraacetic acid, disodium salt	(CAS No) 6381-92-6 (EC-No.) 205-358-3	0.11873	Not classified
tertiary-octylphenoxypoly(ethoxyethanol)	(CAS No) 9036-19-5	0.08582	Eye Irrit. 2, H319 Skin Irrit. 2, H315
Human HDL Cholesterol		0.075	Not classified
Sodium Chloride	(CAS No) 7647-14-5 (EC-No.) 231-598-3	0.07307	Not classified
METHYLPARABEN	(CAS No) 99-76-3 (EC-No.) 202-785-7	0.03939	Not classified
chloramphenicol	(CAS No) 56-75-7 (EC-No.) 200-287-4	0.01478	Carc. 1B, H350 Repr. 2, H361d
SUCROSE	(CAS No) 57-50-1 (EC-No.) 200-334-9	0.0136	Not classified
SERUM ALBUMIN	(CAS No) 9048-46-8 (EC-No.) 232-936-2	0.012657	Not classified
2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol	(CAS No) 4719-04-4 (EC-No.) 225-208-0 (EC index no) 613-114-00-6	0.000038 - 0.000041	Acute Tox. 4 (Oral), H302 Skin Sens. 1, H317
Piperacillin			Not classified
Name	Product identifier	Specific concentration limits	
2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol	(CAS No) 4719-04-4 (EC-No.) 225-208-0 (EC index no) 613-114-00-6	(C >= 0.1) Skin Sens. 1, H317	

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

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3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: If you feel unwell, seek medical advice. Under normal conditions of use, no adverse effects to health have been observed.
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	: If skin irritation occurs: Get medical advice/attention. Gently wash with plenty of soap and water.
First-aid measures after eye contact	: Not expected to present a significant eye contact hazard under anticipated conditions of normal use.
First-aid measures after ingestion	: Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

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

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries after inhalation	: None under normal use.
Symptoms/injuries after skin contact	: None under normal use.
Symptoms/injuries after eye contact	: None under normal use.
Symptoms/injuries after ingestion	: None under normal use.
Symptoms/injuries upon intravenous administration	: No effects known. None under normal use.
Chronic symptoms	: None under normal use.

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	: Water spray. Foam.
Unsuitable extinguishing media	: No unsuitable extinguishing media known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: No direct or indirect fire hazard identified.
Explosion hazard	: No direct explosion hazard.
Reactivity in case of fire	: No known hazards/None known.
Hazardous decomposition products in case of fire	: fume.

5.3. Advice for firefighters

Precautionary measures fire	: Evacuate area. Stop leak if safe to do so.
Firefighting instructions	: Eliminate all ignition sources if safe to do so. Evacuate area. Use water spray or fog for cooling exposed containers.
Protection during firefighting	: Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No open flames. No smoking.
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6.1.1. For non-emergency personnel

Protective equipment	: Protective clothing as deemed necessary.
Emergency procedures	: Evacuate unnecessary personnel. Keep containers closed. No open flames, no sparks, and no smoking.
Measures in case of dust release	: No effects known.

6.1.2. For emergency responders

Protective equipment	: Use personal protective equipment as required.
Emergency procedures	: Contain any material as necessary.

6.2. Environmental precautions

Avoid release to the environment.

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6.3. Methods and material for containment and cleaning up

For containment	: Collect spillage and/or debris.
Methods for cleaning up	: This material and its container must be disposed of in a safe way, and as per local legislation. Carefully collect the spill/leftovers.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: No known hazards/None known.
Precautions for safe handling	: Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke when using this product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep out of reach of children. Keep container tightly closed. Observe normal hygiene standards. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Wear personal protective equipment.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Comply with applicable regulations.
Storage conditions	: Keep container closed when not in use. Keep cool. Protect from sunlight. Keep only in original container. Protect from sunlight. Store in a dry place. Store in a closed container. Direct sunlight.
Incompatible products	: None known.
Incompatible materials	: Direct sunlight. Sources of ignition.
Heat and ignition sources	: Away from heat sources.
Prohibitions on mixed storage	: None known.
Storage area	: Keep container as directed in product literature.
Special rules on packaging	: meet the legal requirements. Keep only in original container. Proper handling and disposal methods should be established by the laboratory in accordance with local, state, federal and national regulations.
Packaging materials	: No data available.

7.3. Specific end use(s)

None known.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls	: Wear recommended personal protective equipment.
Personal protective equipment	: Avoid all unnecessary exposure. Gloves. In case of splash hazard: safety glasses. Protective clothing.



Thermal hazard protection	: Not applicable.
Environmental exposure controls	: Avoid release to the environment.
Consumer exposure controls	: Avoid contact during pregnancy/while nursing.
Other information	: Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: No data available
Odour	: No data available
Odour threshold	: No data available

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pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Not applicable. The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Sodium Chloride (7647-14-5)	
LD50 oral rat	3000 mg/kg (Rat; Experimental value; 3550 mg/kg bodyweight; Rat; Experimental value)
LD50 dermal rabbit	> 10000 mg/kg (Rabbit; Experimental value)
ATE CLP (oral)	3000 mg/kg body weight
magnesium chloride (7786-30-3)	
LD50 oral rat	2800 mg/kg (Rat)
ATE CLP (oral)	2800 mg/kg body weight
2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (4719-04-4)	
LD50 oral rat	763 mg/kg (Rat)
LD50 dermal rat	> 2000 mg/kg (Rat)
glucose, D- (50-99-7)	
LD50 oral rat	25800 mg/kg (Rat)
tertiary-octylphenoxypoly(ethoxyethanol) (9036-19-5)	
LD50 oral rat	4190 mg/kg (Rat)
LD50 dermal rabbit	> 3000 mg/kg (Rabbit)
Ethylenediamine tetraacetic acid, disodium salt (6381-92-6)	
LD50 oral rat	> 2000 mg/kg (Rat)

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2,2',2''-(hexahydro-1,3,5-triazine-1,3,5-triyl)triethanol (4719-04-4)	
LD50 dermal rabbit	> 5000 mg/kg (Rabbit)
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

chloramphenicol (56-75-7)	
EC50 Daphnia 1	1.085 mg/l (LC50; 24 h)
Sodium Chloride (7647-14-5)	
LC50 fish 2	5840 mg/l (LC50; ASTM; 96 h; Lepomis macrochirus; Flow-through system; Fresh water; Experimental value)
Threshold limit algae 2	2430 mg/l (EC50; OECD 201: Alga, Growth Inhibition Test; 120 h; Algae; Static system; Fresh water; Experimental value)
magnesium chloride (7786-30-3)	
LC50 fish 1	16500 mg/l (LC50; 96 h; Gambusia affinis)
EC50 Daphnia 1	3190 mg/l (EC50; OECD 202: Daphnia sp. Acute Immobilisation Test; 24 h; Daphnia magna)
tertiary-octylphenoxypoly(ethoxyethanol) (9036-19-5)	
Threshold limit algae 1	10 mg/l (EC50; 336 h)
Ethylenediamine tetraacetic acid, disodium salt (6381-92-6)	
LC50 fish 1	320 mg/l (LC50; 96 h)
EC50 Daphnia 1	> 100 mg/l (EC50; 24 h)

12.2. Persistence and degradability

4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid (7365-45-9)	
Persistence and degradability	Biodegradability in water: no data available.
chloramphenicol (56-75-7)	
Persistence and degradability	Biodegradable in water.
Sodium Chloride (7647-14-5)	
Persistence and degradability	Biodegradability: not applicable. No (test)data on mobility of the substance available.
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
magnesium chloride (7786-30-3)	
Persistence and degradability	Biodegradability: not applicable.
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
glucose, D- (50-99-7)	
Persistence and degradability	Readily biodegradable in water.
ThOD	1.07 g O ₂ /g substance
tertiary-octylphenoxypoly(ethoxyethanol) (9036-19-5)	
Persistence and degradability	Biodegradability in water: no data available.
Ethylenediamine tetraacetic acid, disodium salt (6381-92-6)	
Persistence and degradability	Not readily biodegradable in water.
Biochemical oxygen demand (BOD)	0.01 g O ₂ /g substance
Aminotransferase, alanine (9000-86-6)	
Persistence and degradability	Biodegradability in water: no data available.

12.3. Bioaccumulative potential

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chloramphenicol (56-75-7)	
Bioaccumulative potential	No bioaccumulation data available.
4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid (7365-45-9)	
Bioaccumulative potential	No bioaccumulation data available.
Sodium Chloride (7647-14-5)	
Log Pow	-3 (Calculated)
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).
magnesium chloride (7786-30-3)	
Bioaccumulative potential	No bioaccumulation data available.
glucose, D- (50-99-7)	
Log Pow	-3.24 (Experimental value)
Bioaccumulative potential	Bioaccumulation: not applicable.
tertiary-octylphenoxypoly(ethoxyethanol) (9036-19-5)	
Bioaccumulative potential	No bioaccumulation data available.
Ethylenediamine tetraacetic acid, disodium salt (6381-92-6)	
Bioaccumulative potential	No bioaccumulation data available.
Aminotransferase, alanine (9000-86-6)	
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Waste disposal recommendations	: Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.
Additional information	: Clean up even minor leaks or spills if possible without unnecessary risk.
Ecology - waste materials	: Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

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RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (ADN) : Not applicable

Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

Not subject to ADN : No

- Rail transport

Carriage prohibited (RID) : No

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

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 Annex XVII restrictions

Alere LDX Controls 2 is not on the REACH Candidate List

Contains no substance on the REACH candidate list

Alere LDX Controls 2 is not on the REACH Annex XIV List

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

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15.2. Chemical safety assessment

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U.S. - California - Proposition 65 - Carcinogens List	No
U.S. - California - Proposition 65 - Developmental Toxicity	No
U.S. - California - Proposition 65 - Reproductive Toxicity - Female	No
U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No

SECTION 16: Other information

Training advice : Normal use of this product shall imply use in accordance with the instructions on the packaging.

Other information : Store and handle according to packaged instructions.

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

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Carc. 1B	Carcinogenicity Category 1B
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Repr. 2	Reproductive toxicity Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
H302	Harmful if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H350	May cause cancer
H361d	Suspected of damaging the unborn child
R22	Harmful if swallowed
R36/38	Irritating to eyes and skin
R43	May cause sensitization by skin contact
R45	May cause cancer
R63	Possible risk of harm to the unborn child
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II)

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