



Safety Data Sheet

According to the regulatory (CE) n° 1907/2006 [REACH] and (CE) n° 1272/2008 [CLP]

Revision date: 29/09/2020

Version: 2.5

SECTION 1: Identification of the substance/mixture and the supplier/manufacturer

1.1. Product identifier

LDBIO DIAGNOSTICS WESTERN BLOT KITS

Trade name/designation	Product No
ASPERGILLUS WB IgG	ASP-WB12G – ASP-WB24G – ASP-WB96G
CHAGAS WB IgG	CHA-WB12G – CHA-WB24G – CHA-WB96G
CYSTICERCOSIS WB IgG	CYS-WB12G – CYS-WB24G – CYS-WB96G
ECHINOCOCCUS WB IgG	ECH-WB12G – ECH-WB24G – ECH-WB96G
FASCIOLA ES WB IgG	FAS ES-WB12G – FAS ES-WB24G – FAS ES-WB96G
LEISHMANIA WB IgG	LES-WB12G – LES-WB24G – LES-WB96G
LDBIO TOXO II IgG	TOXO II-12G – TOXO II-24G – TOXO II-96G
SCHISTO II WB IgG	SCH II-WB12G – SCH II-WB24G – SCH II-WB96G
TOXOCARA WB IgG	TXA-WB12G – TXA-WB24G – TXA-WB96G
TOXOPLASMA WB IgG IgM	TOP-WB12GM – TOP WB24GM – TOP WB96GM
TRICHINELLA ES WB IgG	TRI ES-WB12G – TRI ES-WB24G – TRI ES-WB96G

1.2. Composition/information on components

The product is the set of LDBIO Diagnostics western blot kits (see product identifier table above) which include several components named R1, R2, R3, R4, R6, R10, (see see the corresponding kit instructions for use), of identical composition and which do not contain any hazardous substance.

Each of the above product references also contains a vial of substrate R5.

Reagent R5, SUBSTRATE, is a mixture of hazardous components whose classification according to Regulation (EC) No. 1272/2008 [CLP] can be obtained in section 3. Section 2 "Labeling Elements" specifies the resulting labeling for the R5 vial and the kit.

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

Recommended Use: In Vitro Diagnosis – for professional users only

1.4. Details of the supplier of the safety data sheet

Supplier

LDBIO DIAGNOSTICS

19 A rue Louis Loucheur

69009 Lyon, France

Phone number : +33 4 78 83 34 87

Fax number : +33 4 78 83 34 30

Email : contact@ldbiodiag.com

Web site : www.ldbiodiagnostics.com

Manufacturer

LDBIO DIAGNOSTICS
 19 A rue Louis Loucheur
 69009 Lyon, France
 Phone number : +33 4 78 83 34 87
 Fax number : +33 4 78 83 34 30
 Email : contact@ldbiodiag.com
 Web site : www.ldbiodiagnostics.com

Emergency telephone

Telephone: 112 (emergency service) - 999 or Call a POISON CENTRE or doctor/physician

SECTION 2: Hazards identification**2.1 substance or mixture identifier**

Trade name/designation:	Substrate (included in the WB kit)
Product No.:	R5
EC identification No:	not applicable
REACH identification No:	not applicable
CAS No:	not applicable
Other means of identification:	no data available

2.2 Classification of the substance or mixture**2.2.1 GHS Classification in accordance with (CE) N° 1272/2008 [CLP]**

Hazard classes and hazard categories	Code
Specific target organ toxicity, single exposure, STOT SE2	H371

2.3 Label elements**2.3.1 Labelling in accordance with (CE) N° 1272/2008 [CLP]**

- **Hazard pictograms**



- **Signal word:**
Warning

Note: Because of the small size of the vial, ≤125ml, and in accordance with EC Regulation N° 1272/2008 [CLP], only the pictogram appears on the packaging. It appears on the external packaging of the together with the mixture name "R5" and on the vial.

- **Hazard statements**

Code	Hazard statements
H371	May cause damage to organs.

- **Precautionary statements**

Code	Prevention
P260 P264 P270 P280	Do not breathe spray, wash hands thoroughly after handling, Do not eat, drink or smoke when using the product. Wear protective gloves and protective clothing..
	Intervention
P309 P311	IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician...
	Storage
P405	Store locked up
	Disposal
P501	Dispose of contents and container in accordance with relevant regulations.

- **Hazards not otherwise classified (HNOC)**

none

- **Annotation in the IFU:**

EUH 210 - Material Safety Data Sheet available on request

SECTION 3: Composition / information on ingredients

3.1 Substances

not applicable

3.2 Mixtures (SUBSTRATE – R5)

Hazardous ingredients Classification according to (CE) N° 1272/2008 [CLP]

Substance name	Substance identifier	Hazard classes and hazard categories of the substance	[C]	Hazard classes and hazard categories of the mixture (R5)
Methanol	n°CAS: 67-56-1 N°CE: 200-659-6 REACH Registration Number: 01-2119433307-44-XXXX	Flam. Liq. 2 - H225 Acute Tox. Oral 3 - H301+H311+H331 STOT SE 1 - H370	<5%	May cause damage to organs STOT SE 2 - H371

SECTION 4: First aid measures

4.1 General information

If exposed or if you feel unwell: Call a POISON CENTER or doctor/physician. If unconscious place in recovery position and seek medical advice. Never give anything by mouth to an unconscious person or a person with cramps. Change contaminated, saturated clothing. Do not leave affected person unattended.

After inhalation

Call a POISON CENTER/doctor. Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration.

In case of skin contact

After contact with skin, wash immediately with plenty of water and soap. Remove contaminated, saturated clothing immediately. In case of skin reactions, consult a physician.

After eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Protect uninjured eye. Remove contact lenses, if present and easy to do. Continue rinsing.

In case of ingestion

If accidentally swallowed rinse the mouth with plenty of water (only if the person is conscious) and obtain immediate medical attention. Do NOT induce vomiting. Give nothing to eat or drink.

4.2 Most important symptoms/effects, acute and delayed

no data available

4.3 Indication of any immediate medical attention and special treatment needed

no data available

4.4 Self-protection of the first aider

First aider: Pay attention to self-protection!

4.5 Information to physician

no data available

SECTION 5: Firefighting measures**5.1 Extinguishing media****Suitable extinguishing media**

The product itself is not flammable.
Co-ordinate fire-fighting measures to the fire surroundings.

Extinguishing media which must not be used for safety reasons

no restriction

5.2 Specific hazards arising from the chemical

In case of fire may be liberated:
Pyrolysis products, toxic

5.3 Advice for firefighters

Protective equipment and precautions for firefighters
Wear a self-contained breathing apparatus and chemical protective clothing if necessary.

Additional information

Standard procedure for chemical fires: Use extinguishing media appropriate to local conditions and the surrounding environment.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

In case of major fire and large quantities: Remove persons to safety.

6.2 Environmental precautions

Discharge into the environment must be avoided.

6.3 Methods and material for containment and cleaning up

Spilled product must never be returned to the original container for recycling. Collect in closed and suitable containers for disposal.

6.4 Additional information

Clear spills immediately.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

All work processes must always be designed so that the following is as low as possible: Inhalation, ingestion, skin contact, eye contact. Do not eat, drink or smoke in the work area. Handle in accordance with good laboratory practice.

7.2 Conditions for safe storage, including any incompatibilities

Recommended storage temperature: see operating instructions and labels.
Storage class: no data available.

7.3 Specific end use(s)

In vitro diagnostics. For professional users only

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredient (Designation)	Regulatory information	Country	Country Limit value type (country origin)	Limit value
Methanol	2006/15/EC	EU	LTV	260 mg/m ³ - 200 ppm
Methanol	INRS	FR	VLCT	1300 mg/m ³ - 1000 ppm
Methanol	INRS	FR	VLEP	260 mg/m ³ - 200 ppm

8.2 Engineering controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment. If handled uncovered, arrangements with local exhaust ventilation have to be used.

Personal protection equipment (PPE)

Wear suitable protective clothing. When handling with chemical substances, CE approved protective clothing must be worn.

Eye/face protection

Eye glasses with side protection (norms DIN/EN: DIN EN 166)

Skin protection

Wear suitable gloves. When handling with chemical substances, CE approved protective gloves must be worn (norms DIN/EN: EN ISO 374). In the case of wanting to use the gloves again, clean them before taking off and air them well. Check leak tightness/impermeability prior to use.

Respiratory protection

Respiratory protection necessary at: aerosol or mist formation If exposure limits are exceeded or irritation is experienced, CE approved respiratory protection should be worn (norms NF EN 136/140).

Additional information

Wash hands before breaks and after work. Avoid contact with skin and eyes. When using do not eat, drink or smoke. Provide eye shower and label its location conspicuously.

Environmental exposure controls

no data available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- (a) Appearance
- | | |
|-----------------|--------|
| Physical state: | liquid |
| Color: | yellow |
- (b) Odour: no data available
- (c) Odour threshold: no data available

Safety relevant basic data

(d) pH:	no data available
(e) Melting point/freezing point:	no data available
(f) Initial boiling point and boiling range:	no data available
(g) Flash point:	no data available
(h) Evaporation rate:	no data available
(i) Flammability (solid, gas):	not applicable
(j) Flammability or explosive limits	
Lower explosion limit:	no data available
Upper explosion limit:	no data available
(k) Vapour pressure:	no data available
(l) Vapour density:	no data available
(m) Relative density:	no data available
(n) Solubility(ies)	
Water solubility (g/L):	no data available
Soluble (g/L) in Ethanol:	no data available
(o) Partition coefficient: n-octanol/water:	no data available
(p) Auto-ignition temperature:	no data available
(q) Decomposition temperature:	no data available
(r) Viscosity	
Kinematic viscosity:	no data available
Dynamic viscosity:	no data available
(s) Explosive properties:	not applicable
(t) Oxidising properties:	not applicable

9.2 Other information

Bulk density:	not applicable
Refraction index:	no data available
Dissociation constant:	no data available
Surface tension:	no data available
Henry constant:	no data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

no data available

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

no data available

10.7 Additional information

no data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute effects

Acute oral toxicity:

AMP (2-Amino-2-methylpropanol) - LD50: > 2900 mg/kg - Rat - (CHP)

Methanol - LD50: > 5628 mg/kg - Rat - (IUCLID)

Methanol - LDLo: > 143 mg/kg - Human - (RTECS)

Acute dermal toxicity:

AMP (2-Amino-2-methylpropanol) - LD50: < 2000 mg/kg - Rabbit - (CHP)

Methanol - LD50: > 15800 mg/kg - Rabbit

Acute inhalation toxicity:

Methanol - TClO: > 160 ppm (4h) - Human

Irritant and corrosive effects

Primary irritation to the skin: not applicable

Irritation to eyes:

not applicable

Irritation to respiratory tract:

not applicable

Respiratory or skin sensitization

In case of skin contact: not sensitising

After inhalation: not sensitising

STOT-single exposure

May cause damage to organs.

STOT-repeated exposure

not applicable

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity

No indications of human carcinogenicity exist.

Germ cell mutagenicity

No indications of human germ cell mutagenicity exist.

Reproductive toxicity

No indications of human reproductive toxicity exist.

Aspiration hazard

not applicable

Other adverse effects

no data available

Additional information

no data available

SECTION 12: Ecological information

12.1 Ecotoxicity

Fish toxicity:

Methanol - LC50: 24000 mg/l (96 h) - Poirier, S.H., M.L. Knuth, C.D. Anderson-Buchou, L.T. Brooke, A.R. Lima, and P.J. Shubat 1986. Comparative Toxicity of Methanol and N,N-Dimethylformamide to Freshwater Fish and Invertebrates. Bull.Environ.Contam.Toxicol. 37(4):615-621

Daphnia toxicity:

Methanol - LC50: 3290 mg/l (48 h) - Guilhermino, L., T. Diamantino, M.C. Silva, and A.M.V.M. Soares 2000. Acute Toxicity Test with Daphnia magna: An Alternative to Mammals in the Prescreening of Chemical Toxicity?. Ecotoxicol.Environ.Saf. 46(3):357- 362

Methanol - EC50: 24500 mg/l (48 h) - Randall, T.L., and P.V. Knopp 1980. Detoxification of Specific Organic Substances by Wet Oxidation. J.Water Pollut.Control Fed. 52(8):2117-2130

Algae toxicity:

no data available

Bacteria toxicity:

no data available

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water: no data available

12.4 Mobility in soil:

no data available

12.5 Results of PBT/vPvB assessment

no data available

12.6 Other adverse effects

no data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Appropriate disposal / Product

Dispose according to legislation. Consult the appropriate local waste disposal expert about waste disposal.

Waste code product: no data available

Appropriate disposal / Package

Dispose according to legislation. Handle contaminated packages in the same way as the substance itself.

Additional information

no data available

SECTION 14: Transport information

Land transport (ADR/RID)

No dangerous good in sense of this transport regulation.

Sea transport (IMDG)

No dangerous good in sense of this transport regulation.

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

not relevant

Air transport (ICAO-TI / IATA-DGR)

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

- Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006

- Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

- Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

SECTION 16: Other information

Abbreviations and acronyms

IVD – In Vitro Diagnostic

INRS - The National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases

VLE - Exposure limit value

VME - Average exposure value

ACGIH - American Conference of Governmental Industrial Hygienists

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road AGS - Committee on Hazardous Substances (Ausschuss für Gefahrstoffe)

CLP - Regulation on Classification, Labelling and Packaging of Substances and Mixtures DFG - German Research Foundation (Deutsche Forschungsgemeinschaft)

Gestis - Information system on hazardous substances of the German Social Accident Insurance (Gefahrstoffinformationssystem der Deutschen Gesetzlichen Unfallversicherung)

IATA-DGR - International Air Transport Association-Dangerous Goods Regulations ICAO-TI - International Civil Aviation Organization-Technical Instructions

IMDG - International Maritime Code for Dangerous Goods LTV - Long Term Value

NIOSH - National Institute for Occupational Safety and Health OSHA - Occupational Safety & Health Administration

PBT - Persistent, Bioaccumulative and Toxic

RID - Regulation concerning the International Carriage of Dangerous Goods by Rail STV - Short Term Value

SVHC - Substances of Very High Concern vPvB - very Persistent, very Bioaccumulative

Additional information

Indications of change: 29/09/2020 general update: 29/09/2020

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guidance. The information in this document is based on the present state knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. LDBIO DIAGNOSTICS shall not be held liable for any damage resulting from handling.