

Material safety data sheet

according to Regulation (EC). N°. 1907/2006

Parasitic and mycological diseases complete ELISA kits	Reference
<i>Aspergillus fumigatus</i> IgG ELISA	6100
<i>Toxocara canis</i> IgG ELISA	9200
<i>Ascaris</i> IgG ELISA	9250
<i>Echinococcus multilocularis</i> (Em2-Em18) IgG ELISA	9300
<i>Echinococcus multilocularis</i> (Em18) IgG ELISA	9310
<i>Echinococcus granulosus</i> IgG ELISA	9350
<i>Acanthocheilonema viteae</i> IgG ELISA	9400
<i>Strongyloides ratti</i> IgG ELISA	9450
<i>Leishmania infantum</i> IgG ELISA	9500
<i>Entamoeba histolytica</i> IgG ELISA	9550
<i>Schistosoma mansoni</i> IgG ELISA	9600
<i>Fasciola hepatica</i> IgG ELISA	9650
<i>Taenia solium</i> IgG ELISA	9700
<i>Trichinella spiralis</i> IgG ELISA	9750
<i>Anisakidae</i> IgG ELISA	9800

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

1.1 Product identifier: Parasitic and mycological diseases complete ELISA kits (listed above).

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

Medical device / Laboratory reagents / Immunoassay.

The product is intended for professional use.

These mixtures do not contain nanoparticles in their formulation.

1.3 Details of the supplier of the safety data sheet

Manufacturer/ Distributor:

Bordier affinity products S.A.

Chemin de Chatanerie 2, CH-1023 Crissier, Switzerland

Phone: +41 21 633 31 67

E-mail: cb@bordier.ch,

Web: www.bordier.ch

Further information obtainable from:

Safety representative.

1.4 Emergency phone number:

Please contact the nearest poison emergency center or

112 (day and night)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation EC n° 1272/2008 (CLP):

Physical Hazards: not classified

Health Hazards: not classified

Environmental Hazards: not classified

Classification according to Directive 67/548/EEC or Directive 1999/45/EC:

Not classified

2.2 Label elements:

Hazard pictograms:



Signal word:

Danger

Hazard statements:

H318: Causes serious eye damage

Precautionary statement:

P280: Wear eye protection.

P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing

PBT:

Not applicable

vPvB:

Not applicable

2.3 Others hazards

None

SECTION 3: Composition/information on ingredients

3.1 Substances:

N/A

3.2 Mixtures

Chemical characterization:

Mixtures do not contain hazardous substances in concentration to be declared.

Material contained in the kit (96 assays):

****-01	Breakable ELISA strips sensitized with antigens	96	wells
****-02	Dilution buffer (10 x) concentrate	50	ml
****-03	Washing solution (10 x) concentrate	50	ml
****-04	Enzyme buffer	50	ml
****-05	Stopping solution (K ₃ PO ₄)	25	ml
****-06	Negative control serum	200	µl
****-07	Weak positive serum (cut off)	200	µl
****-08	Positive control serum	200	µl
****-09	Protein A-alkaline phosphatase conjugate	300	µl
****-10	Phosphatase substrate	20	tablets

Description:

Dilution buffer^{****-02} contains sodium azide and thiomersal.

Washing solution n^{****-03} contains sodium azide.

Enzyme buffer n^{****-04} contains sodium azide.

Stopping solution n^{****-05} contains potassium phosphate, tribasic.

Control sera n^{****-06}, -07 and -08 contain sodium azide and thiomersal.

Conjugate n^{****-09} contains sodium azide.

CAS-Nr.	Description of the hazardous ingredients	R-phrases 67/548/EEC	H-mentions EC n° 1272/2008 (CLP)	Concentration
26628-22-8	Sodium azide	T+; R28; R32 N; R50/53	Acute Tox. 2; H300, H310, H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	<0.1%
54-64-8	Thiomersal	T+; R26/27/28; R33 N; R50/53;	Acute Tox. 2; H300, H310, H330, H373 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	<0.02%

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27176-10-9	Potassium phosphate tribasic monohydrate	C; R38; R41	Skin irritation 2; H315 Serious eye damage 1; H318	10%
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Additional information: The control sera are of animal origin (rabbit and dog only for product 9500) and should be handled with care as potentially infectious.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: No special measures required.
After inhalation: Not applicable.
After skin contact: Wash immediately with plenty of water.
After eye contact: Rinse immediately with plenty of water and seek medical advice.
After swallowing: Seek medical advice immediately.

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

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: There is no specific antidote available. Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: Extinguishing media - for small fires, Use water spray or alcohol resistant foam, dry powder or carbon dioxide (CO₂).
Extinguishing media - for large fires, alcohol resistant foam or water spray.

Unsuitable extinguishing media: Do not use a concentrated water jet, which could spread the fire.

5.2 Special hazards arising from the substance or mixture:

No further relevant information available.

5.3 Advice for firefighters

Special protective equipment for firefighters:

It is recommended that firefighters wear self-contained breathing apparatus when fires are of chemical origin.

Additional information: Do not allow contaminated firefighting water to enter drains or water courses.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment, and emergency procedures:

Keep away from food, drinks, and animal feeding stuffs.
Wear suitable protective clothing.

6.2 Environmental precautions:

Must be disposed as hazardous waste.
Avoid release to the environment.

6.3 Methods and material for containment and cleaning up:

Contain spill. Clean carefully with absorbent paper and dispose of it according to regulations. (see section 13).

6.4 Reference to other sections:

Where appropriate, reference will be made to headings 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling: No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Tips for clustered storage: Not required.

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Requirements to be met by storerooms and containers:

No special requirements.

7.3 Specific end use(s)

Additional storage requirements: Not required.

Storage class: None.

Specific end use(s): No further relevant information available.

SECTION 8: Exposure controls and personal protection

8.1 Control parameters:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

Additional tips for the design of technical facilities:

Not required

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information:

The list that was in effect during the creation of this document was used as basis.

General safety and hygiene- measures:

Keep away from food and drinks.

Take off dirty and soaked clothes immediately.

Wash hands before breaks and after work is completed.

Respiratory protection:

Not required.

Hand protection:

It is recommended to wear disposable gloves for protection.

Material of gloves:

The quality of the protective gloves must be chosen as a function of the specific working place concentration and quantity of hazardous substances. The glove material has to be impermeable and resistant to the product/substance/preparation.

Eye protection:

If properly used not required. Recommended during refilling.

Body protection:

Lab coat.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Form: Liquid, dried or solid

Colour: Different according to colouring

Odour: Odourless

Odour threshold: Not available

Melting point / range: Not available

Boiling point / range: Not available

Freezing point / range: Not available

Flashpoint, flammability: Not flammable

Ignition point: Not ignitable

Self-ignitability: Not self-ignitable

Explosion hazard: The product is not explosive

Explosion limits: Not available

Vapor pressure at 20°C: Not available

Density at 20°C: Not available

Solubility in water: Not applicable

9.2 Other information: No further relevant information available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity:** No further relevant information available.
- 10.2 Chemical stability:** Stable under normal conditions
- 10.3 Possibility of hazardous reactions:** No dangerous reactions known.
- 10.4 Conditions to be avoided:** No degradation if used according to labelling.
- 10.5 Incompatible materials:** No further relevant information available.
- 10.6 Dangerous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

The relevant hazard classes, for which information shall be provided, are:

	Sodium azide CAS # 26628-22-8	Potassium phosphate tribasic monohydrate CAS # 27176-10-9	Thimerosal CAS # 54-64-8
(a) acute toxicity	LD50 Oral - Rat - 27 mg/kg Remarks: (RTECS) LC50 Inhalation - Rat - male and female - 4 h - 0,054 - 0,52 mg/l (US-EPA) LD50 Dermal - Rabbit - 20 mg/kg Remarks: (RTECS)	LD50 Oral - Rat - 4.500 mg/kg LD50 Dermal - Rabbit - 4.640 mg/kg	Oral: No data available Acute toxicity estimate Inhalation - 4 h - 0,051 mg/l (Expert judgment) Acute toxicity estimate Dermal - 5,1 mg/kg (Expert judgment)
(b) skin corrosion/irritation	Skin - In vitro study Result: No skin irritation (OECD Test Guideline 439)	Skin - Rabbit Result: Skin irritation	No data available
(c) serious eye damage/irritation	Eyes - Bovine cornea Result: No eye irritation - 4 h (OECD Test Guideline 437)	Eyes - Rabbit Result: Severe eye irritation	No data available
(d) respiratory or skin sensitization	Local lymph node assay (LLNA) - Mouse Result: negative (OECD Test Guideline 429)	No data available	No data available
(e) germ cell mutagenicity	Test Type: Mutagenicity (mammal cell test): chromosome aberration. Test system: Chinese hamster ovary cells. Metabolic activation: with and without metabolic activation. Method: OECD Test Guideline 473. Result: negative. Test Type: unscheduled DNA synthesis assay. Test system: Chinese hamster lung cells. Metabolic activation: without metabolic activation. Method: OECD Test Guideline 482. Result: negative. Test Type: sister chromatid exchange assay. Test system: Chinese hamster ovary cells. Metabolic activation: without metabolic activation. Method: OECD Test Guideline 479. Result: negative.	No data available	Test Type: Ames test Test system: Salmonella typhimurium Result: negative Remarks: (National Toxicology Program)
(f) carcinogenicity	No data available	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.	No data available
(g) reproductive toxicity	No data available	No data available	No data available
(h) STOT-single exposure	No data available	No data available	No data available
(i) STOT-repeated exposure	No data available	No data available	No data available
(j) aspiration hazard:	Oral - May cause damage to organs through prolonged or repeated exposure. - Brain	No data available	No data available
Additional Information	RTECS: VY8050000 Nausea, Headache, Vomiting, Laboratory experiments in animals have shown sodium azide to produce a profound	RTECS: TC8450000	To the best of our knowledge, the chemical, physical, and

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	hypotensive effect, demyelination of myelinated nerve fibers in the central nervous system, testicular damage, blindness, attacks of rigidity, and hepatic and cerebral effects. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.		toxicological properties have not been thoroughly investigated. Danger of cumulative effects.
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Primary irritant effect:

on the skin: None.

on the eye: Component n°****-05 is irritant.

Sensitization:

No sensitizing effect known.

Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

SECTION 12: Ecological information

12.1 Aquatic toxicity:

No further relevant information available.

12.2 Persistence and degradability:

No further relevant information available.

12.3 Bio accumulative potential:

No further relevant information available.

12.4 Mobility in soil:

No further relevant information available.

Water hazard class 1 (German regulation): slightly hazardous for water. Do not allow undiluted products and large amounts to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT:

Not applicable.

vPvB:

Not applicable.

12.6 Endocrine disrupting properties:

No further relevant information available.

12.7 Other adverse effects:

No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Products:

Cannot be disposed with household waste.

Cannot reach sewage system.

Should be disposed in hazardous waste container.

Contaminated packaging:

Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN number or ID number

UN-Number:

-

UN proper shipping name:

-

14.2 UN proper shipping name

Transport by road/rail ADR/RID:

No dangerous good in sense of this transport regulation.

Transport by sea IMDG:

No dangerous good in sense of this transport regulation.

Transport by air IATA-DGR and ICAO-TI:

No dangerous good in sense of this transport regulation.

14.3 Transport hazard class:

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14.4 Packing group:

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14.5 Environmental hazards:

No

14.6 Special precautions for user:

Not applicable.

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14.7 Transport in bulk according to annex II of MARPOL73/78 and the IBC Code:

Not applicable.

Transport/Additional information: Not dangerous according to the above specifications.

This product is part of a kit. Information in this section refers to the kit as a whole.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture **Classification according to EU-Directives:**

The product is classified and labelled according to EU-guidelines.

Code letter and hazard designation of product:

R41.

Hazard-determining components for labelling:



R-phrases:

R 41: Risk of serious damage to eyes.

S-phrases:

None.

Water hazard class:

Water hazard class 1 (German regulation): slightly hazardous for water.

15.2 Chemical Safety Assessment:

For this product a chemical safety assessment was not carried out.

SECTION 16: Other information

Full text of R-phrases and H-statements appearing in point 3:

R 26: Very toxic by inhalation

R 27: Very toxic in contact with skin

R 28: Very toxic if swallowed

R 32: Contact with acids liberates very toxic gas

R 33: Danger of cumulative effects

R 38: Provokes the skin

R 41: Risk of serious damage to eyes

R 50: Toxic to aquatic organisms

R 53: May cause long-term adverse effects in the aquatic environment

H 300: Fatal if swallowed

H 310: Fatal in contact with skin

H 315: Cause skin irritation

H 318: Cause serious eye damage

H 330: Fatal if inhaled

H 373: May cause damage to organs through prolonged or repeated exposure

H 400: Very toxic to aquatic life

H 410: Very toxic to aquatic life with long-lasting effects

Full text for other abbreviations:

AcuteTox.: Acute toxicity

Aquatic Acute: Short-term (acute) hazard to the aquatic environment

Aquatic Chronic: Long-term (chronic) hazard to the aquatic environment

Eye Dam.: Serious eye damage

Eye Irrit.: Eye irritation

Skin Irrit.: Skin irritation

Skin Sens.: Skin sensitization

STOT SE: Specific target organ toxicity - single exposure

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CH SUVA: Switzerland. Workplace exposure limit values
CH SUVA / VME: average exposure value

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