



## DIAGNOSTIC AUTOMATION, INC.

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# MATERIAL SAFETY DATA SHEET

## Bordetella Pertussis IgG ELISA kit

### 1. IDENTIFICATION OF THE PREPARATION AND COMPANY.

#### 1.1. Identification of the product:

Product name: **Bordetella Pertussis IgG ELISA kit**

Product classification: In-vitro diagnostics

Product number: 5118-8

#### 1.2. Components:

- a. Microtiter Plate
- b. Substrate Solution
- c. Conjugate
- d. Washing Solution (10X Concentrate)
- e. Sample Diluent
- f. Calibrators
- g. Stop Solution

**Note:** Concerning safety the a. Microtiter Plate is inoffensive and for this reason not part of this document. The mixtures b.—f., due to coincident categorization, are combined as the group A. The Mixture g.(Stop Solution) is treated as the group B in this document.

#### 1.3. Manufacturer identification

Company Name: **Diagnostic Automation, Inc.**

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Emergency Telephone number: Please contact the local hospitals.

## 2. HAZARDS IDENTIFICATION

### 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

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#### Group A

**Classification according to Directive 67/548/EEC or Directive 1999/45/EC:** No classification applicable.

**Classification according to regulation (EC) No 1272/2008:** This mixture are not classified according to the CLP regulation.

**Information concerning particular hazards for human and environment:** The mixture do not have to be labeled due to the calculation procedure of the “General Classification guideline for preparations of the EU” in the latest version.

**Classification System:** The mixtures are classified as non hazardous according to the criteria of Directive 67/548/EEC and Directive 1999/45/EC or Regulation(EC) No 1272/2008.

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#### Group B

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

Xi, Irritant

R36/38

Irritating to eyes and skin

**Classification according to regulation (EC) No 1272/2008:**

Skin Irrit.2

H315

Causes skin irritation

Eye Irrit.2

H319

Causes serious eye irritation

**Information concerning particular hazards for human and environment:** The mixture has to be labelled due to the calculation procedure of the “General Classification guideline for preparations of the EU” in the latest valid version.

**Classification System:** The classification is according to the latest editions of the EU lists, and extended by company and literature data.

### 2.2 LABEL ELEMENTS

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#### Group A

**Labeling according to regulation (EC) No 1272/2008:** Void

**Hazard Pictograms:** Void

**Signal Word:** Void

**Hazard Statements:** Void

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#### Group B

**Labeling according to regulation (EC) No 1272/2008:** The product is classified and labelled according to the CLP regulation

#### Hazard Pictograms:



GHS05

**Signal Word:** Warning

**Hazard Statements:**

H315 Causes skin irritation  
H319 Causes serious eye irritation

**Precautionary Statements:**

P280 Wear protective gloves/protective clothing/eye protection/face 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.  
P362 Take off contaminated clothing and wash before reuse.  
P332+P313 If skin irritation occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.

**2.3 OTHER HAZARDS**

**Group A/B**

All chemicals are potentially dangerous. They should only be handled by specially trained personnel.

**PBT:** Not applicable  
**vPvB:** Not applicable

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Group A**

**Chemical Characterization: Mixtures**

**Description:** Mixtures of substances with nonhazardous additions.

**Dangerous Components:** Void.

**Additional Information:** For the wording of the listed risk phrases refer to section 16.

**Group B**

**Chemical Characterization: Mixtures**

**Description:** Aqueous solution.

**Dangerous Components:**

<b>CAS No.:</b>	7664-93-9
<b>DESCRIPTION:</b>	Sulfuric acid
<b>EINECS:</b>	231-639-5
<b>INDEX NUMBER:</b>	016-020-00-8
<b>ELEMENTAL FORMULA:</b>	H <sub>2</sub> SO <sub>4</sub>
<b>MOLAR MASS:</b>	98.08
<b>CONCENTRATION IN MIXTURE:</b>	0.5M

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



C

**Classification according to regulation (EC) No 1272/2008:**



R35  
Met Corr. 1  
Skin Corr. 1A  
H290, H314

**Additional Information:** For the wording of the listed risk phrases refer to section 16.

## 4. FIRST AID MEASURES

### Group A/B



### 4.1 DESCRIPTION OF FIRST AID MEASURES

**General Information:**

First aider: Pay attention for self protection!!  
Remove any clothing soiled by the product.

**After Inhalation:**

Remove to fresh air. If breathing is difficult, give oxygen. Seek medical advice immediately.

**After skin contact:**

Immediately rinse with water. After massive or prolonged skin contact: Seek medical advice.

**After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

**After swallowing:**

Rinse out mouth and drink a glass of water. Do not induce vomiting. If there is any trouble seek medical help.

### 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

No further relevant information available.

## 5. FIREFIGHTING MEASURES

### Group A/B

### 5.1 EXTINGUISHING MEDIA

**Suitable Extinguishing Agents:**

Use fire extinguishing methods suitable to surrounding conditions. CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

**For Safety Reasons Unsuitable Extinguishing Agents:**

For this mixture no limitations of extinguishing agents are given.

### 5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

Ambient fire may liberate hazardous vapours.

In the event of fire development of hazardous combustion gases or vapours possible.

In case of fire, the following gases can be released: Sulphur dioxide, carbon monoxide and carbon dioxide.

### **5.3 IMPORTANT ADVICE FOR FIREFIGHTING**

#### **PROTECTIVE EQUIPMENT:**

Wear self-contained respiratory protective device. Wear fully protective suit.

### **6. ACCIDENTAL RELEASE MEASURES**

Group A/B

#### **6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES**

Wear protective clothing. Keep away unprotected persons. Avoid eye or skin contact.

#### **6.2. ENVIRONMENTAL PRECAUTIONS**

Do not allow to enter sewers/ground water or penetrate the soil.

#### **6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP**

Absorb with liquid binding material (sand diatomite, acid binders, universal binders, sawdust).

Dispose of the material according to regulations.

Ensure adequate ventilation.

#### **6.4. VERWEIS AUF ANDERE ABSCHNITTE**

See section 7 for information on safe handling.

See section 8 for information on personal protection requirement.

See section 13 for disposal information.

### **7. HANDLING AND STORAGE**

#### **7.1. PRECAUTIONS FOR SAFE HANDLING**

Group A/B

No special precautions are necessary if used correctly.

##### **Information about Fire-And Explosion Protection:**

No special measures required.

#### **7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES**

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Group A

##### **STORAGE:**

##### **Requirements to be met by Storerooms and Receptables:**

Store at a cool place.

##### **Information About Storage in One Common Storage Facility:**

Store away from foodstuffs.

##### **Further Information about Storage Conditions:**

None.

##### **RECOMMENDED STORAGE TEMPERATURE:**

2-8°C

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## **Group B**

### **STORAGE:**

#### **Requirements to be met by Storerooms and Receptables:**

Store at a cool place.  
Do not store in corrodible metal.  
Provide acid-resistant floor

#### **Information About Storage in One Common Storage Facility:**

Store away from foodstuffs.

#### **Further Information about Storage Conditions:**

None.

#### **RECOMMENDED STORAGE TEMPERATURE:**

2-8°C

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### **7.3. SPECIFIC END USE(S)**

No further relevant information available.

## **8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Additional Information About Design of Technical Facilities:** No further data; see item 7.

### **8.1 CONTROL PARAMETERS**

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#### **Group A**

#### **Ingredient with Limit Values that Require Monitoring At Workplace:**

The mixtures do not contain any relevant quantities of materials with critical values that have to be monitored at the working place.

**Additional Information:** The lists valid during the making were used as basis.

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#### **Group B**

#### **Limit Values that Require Monitoring At Workplace:**

<b>7664-93-9 Sulphuric Acid</b>	
<b>AGW :</b>	0.1 E mg/m <sup>3</sup> 1(l): DFG, EU, H, Y
<b>IOELV(EU):</b>	0.05 mg/m <sup>3</sup>

#### **DNEL Values (Sulphuric Acid):**

<b>Workers</b>		
<b>Long-Term Exposition-Local Effects</b>		
Inhalative	DNEL	0.05mg/m <sup>3</sup> (worker)
<b>Short-Term Exposition-Local Effects:</b>		
Inhalative	DNEL	0.1mg/m <sup>3</sup> (worker)

#### **PNEC Values (Sulphuric Acid)**

<b>PNEC</b>	8.8 mg/L (sewage treatment plant)
	0.002 mg/kg (sea water sediment)
	0.25 mg/L (seawater)
	0.0025mg/L (fresh water)
	0.002 mg/kg (seawater sediment)

**Additional Information:** The lists valid during the making were used as basis.

## 8.2 EXPOSURE CONTROLS

### Group A/B:

#### **Personal Protective Equipment:**

##### **General Protective and Hygienic measures:**

Wash hands before breaks and at the end of work.  
Keep away from foodstuffs, beverages and feed.  
Avoid contact with the eyes and skin.  
Immediately remove all soiled and contaminated clothing.

##### **Individual Protection Measures:**

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

##### **Respiratory Protection:**



Required when vapours are generated

##### **Protection of Hands:**



**Protective gloves** – The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

##### **Material of Gloves:**

##### **Nitrile, thickness: $\geq 0.11$ mm**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

##### **Penetration time of glove material:**

Value of the permeation: Level  $\geq 6$

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

##### **Eye Protection:**



Tightly sealed goggles

**Body Protection:**



Protective work clothing

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES**

**Group A/B**

Property	Calibrators	Substrate Solution	Conjugate	Washing Solution (10X Conc.)	Sample Diluent	Stop Solution(0.5M Sulphuric acid)
<b>General Information</b>						
<b>Appearance:</b>						
<b>Form</b>	Fluid	Fluid	Fluid	Fluid	Fluid	Fluid
<b>Colour:</b>	Blue	Colourless	red	Colourless	Blue	Colourless
<b>Odour:</b>	Odourless	Odourless	Odourless	Odourless	Odourless	odourless
<b>Odour Threshold</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>pH-Value at 25 °C:</b>	6.0-7.4	3.3-3.8	6.2-7.2	6.2-7.2	6.2-7.4	~0.6
<b>Change In Condition:</b>						
<b>Melting Point/range</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Boiling Point/range</b>	100 °C	No information available	100 °C	100 °C	100 °C	100 °C
<b>Flash point:</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Flammability (Solid, gaseous)</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Ignition Temperature</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Decomposition Temperature:</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Self-Igniting:</b>	The mixture is not self-igniting	The mixture is not self-igniting	The mixture is not self-igniting	The mixture is not self-igniting	The mixture is not self-igniting	The mixture is not self-igniting
<b>Danger of Explosion:</b>	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard
<b>Explosion Limits:</b>						
<b>Lower:</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Upper:</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Oxidizing Properties</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Vapour Pressure at 20°C:</b>	No information available	No information available	No information available	No information available	No information available	23 hPa



<b>Density</b>						
<b>Density at 20°C:</b>	No information available	No information available	No information available	No information available	No information available	1.03g/cm <sup>3</sup>
<b>Vapour Density:</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Evaporation rate:</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Solubility in/ Miscibility with water</b>	Fully miscible	Fully miscible	Fully miscible	Fully miscible	Fully miscible	Fully miscible
<b>Partition Coefficient (N-Octanol/Water)</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Viscosity:</b>						
<b>Dynamic:</b>	No information available	No information available	No information available	No information available	No information available	No information available
<b>Kinematic:</b>	No information available	No information available	No information available	No information available	No information available	No information available

## 9.2. OTHER INFORMATION

### Group A/B

No further relevant information available.

## 10. STABILITY AND REACTIVITY

### 10.1 REACTIVITY

#### Group A

No information available.

#### Group B

See section 10.3..

### 10.2. CHEMICAL STABILITY

#### Group A/B

Thermal decomposition / Conditions to be avoided. No decomposition if used and stored according to specifications.

### 10.3. POSSIBILITY OF HAZARDOUS REACTIONS

#### Group A

No hazardous reactions known.

#### Group B

Reacts with alkali (lyes).

### 10.4. CONDITIONS TO AVOID

#### Group A/B

No information available

### 10.5. INCOMPATIBLE MATERIALS

#### Group A/B

No information available.

## **10.6. HAZARDOUS DECOMPOSITION PRODUCTS**

### **Group A/B**

No dangerous decomposition products known. In case of fire see item 5.

## **11. TOXICOLOGICAL INFORMATION**

### **11.1. INFORMATION ON TOXICOLOGICAL EFFECTS**

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#### **Group A**

##### **ACUTE TOXICITY:**

LD/LC50 VALUES RELEVANT FOR CLASSIFICATION:

Quantitative data on the toxicity of the mixtures are not available.

##### **PRIMARY IRRITANT EFFECT:**

###### **ON THE SKIN:**

No irritating effect known.

###### **ON THE EYES:**

No irritating effect known.

###### **AFTER INHALATION:**

No irritating effect known.

###### **SENSITIZATION:**

No sensitizing effects known.

##### **CMR EFFECTS:**

###### **GERM CELL MUTAGENICITY:**

No information available.

###### **CARCINOGENICITY:**

No information available.

###### **REPRODUCTIVE TOXICITY:**

No information available.

##### **ASPIRATION HAZARD:**

No aspiration toxicity classification.

##### **SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:**

The mixtures are not classified as specific target organ toxicant, single exposure.

##### **SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:**

The mixtures are not classified as specific target organ toxicant, repeated exposure.

##### **ADDITIONAL TOXICOLOGICAL INFORMATION:**

We have no description of any toxicological symptoms.

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#### **Group B**

##### **ACUTE TOXICITY:**

LD/LC50 VALUES RELEVANT FOR CLASSIFICATION:

Quantitative data on the toxicity of the mixtures are not available.

##### **PRIMARY IRRITANT EFFECT:**

###### **ON THE SKIN:**

Irritant to skin and mucous membranes.

###### **ON THE EYES:**

Irritant

**AFTER INHALATION:**

Irritant to skin and mucous membranes.

**SENSITIZATION:**

No sensitizing effects known.

**CMR EFFECTS:**

**GERM CELL MUTAGENICITY:**

No information available.

**CARCINOGENICTY:**

No information available.

**REPRODUCTIVE TOXICITY:**

No information available.

**ASPIRATION HAZARD:**

No aspiration toxicity classification.

**SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE:**

The mixtures are not classified as specific target organ toxicant, single exposure.

**SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE:**

The mixtures are not classified as specific target organ toxicant, repeated exposure.

**ADDITIONAL TOXICOLOGICAL INFORMATION:**

We have no description of any toxicological symptoms.

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## **11. 2. FURTHER INFORMATION**

The product should be handled with the care usual when dealing with chemicals.

**Additional Toxicological Information:**

When used and handled according to specifications, the mixtures do not have any harmful effects to our experience and the information provided to us.

## **12. ECOLOGICAL INFORMATION**

### **Group A/B**

### **12.1. TOXICITY**

**AQUATIC TOXICITY:**

Quantitative data on the ecological effect of the mixtures are not available.

### **12.2. PERSISTENCE AND DEGRADABILITY**

No further relevant information available.

### **12.3. BIOACCUMULATIVE POTENTIAL**

No further relevant information available.

### **12.4. MOBILITY IN SOIL**

No further relevant information available.

**ECOTOXICAL EFFECTS:**

**REMARK:**

Water hazard class 1 (German Regulation) (Self-assessment) – Do not allow to enter waters, sewers or soil.

### **12.5. RESULTS OF PBT AND VPVB ASSESSMENT**

**PBT:**

Not applicable.

**VPVB:**

Not applicable.

**12.6. OTHER ADVERSE EFFECTS**

No further relevant information available.

**13. DISPOSAL CONSIDERATIONS**

**Recommendation:**

This material and its container must be disposed of as hazardous waste.

The disposal is regionally differently regulated, therefore the kind of disposal is to be inquired at the responsible authorities.

**UNCLEANED PACKAGING:**

**Recommendation:**

The disposal according to official regulations.

**Recommend cleaning agents:**

Water, if necessary together with cleansing agents.

**14. TRANSPORT INFORMATION**

**14.1 UN-NUMBER**

**ADR, IMDG, IATA:**

Group A: Void

Group B: UN2796

**14.2. UN-PROPER SHIPPING NAME**

**ADR:**

Group A: Void

Group B: “ 2796 Battery fluid, acid or Sulphuric acid with not more than 51 percent acid, N.O.S.”

**IMDG, IATA:**

Group A: Void

Group B: “Sulfuric acid, N.O.S.”

**14.3 TRANSPORT HAZARD CLASS(ES)**

Group A: Void.

Group B:

**ADR:**



**Class:**

8 Corrosive substances

Label:

8

**IMDG, IATA:**



**Class:**  
8 Corrosive substances  
**Label:**  
8

#### 14.4. PACKING GROUP

**IMDG, IATA:**

Group A: Void.

Group B: II

#### 14.5. ENVIRONMENTAL HAZARDS

**MARINE POLLUTANT:**

Group A/B: No.

#### 14.6. SPECIAL PRECAUTIONS FOR USER

Group A: Not applicable.

Group B:

Warning: Corrosive substances.

**DANGER CODE (KEMLER):**

80

**EMS NUMBER:**

F-A, S-B

#### 14.7. TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

**Group A:**

Not applicable.

**UN MODERL REGULATION:** Void

**Group B:**

Not applicable.

**TRANSPORT/ ADDITIONAL INFORMATION (ADR)**

**LIMITED QUANTITIES (LQ)**

5L

**TRANSPORT CATEGORY**

3

**TUNNEL RESTRICTION CODE**

E

**UN MODEL REGULATION:** 2796 Battery fluid, acid or Sulphuric acid with not more than 51 percent acid, N.O.S., 8, II

#### 15. REGULATORY INFORMATION

##### 15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCES OR MIXTURE

**IMPOTANT ABOUT LIMITATION OF USE:** Employment restrictions concerning juveniles must be observed.

**WATER HAZARD:** Slightly hazardous for water.

##### 15.2. CHEMICAL SAFETY ASSESSMENT

A chemical safety assessment has not been carried out.

#### 16. OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

**RELEVANT PHRASES:**

Group A: Void.

Group B:

**PHRASE**

**H315**

**H319**

**R36/38**

**DEFINITION**

Causes Skin irritation

Causes serious eye irritation

Irritating to eyes and skin.

**DEPARTMENT ISSUING MSDS:**

Department R&D

**CONTACT:**

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**ABBREVIATIONS AND ACRONYMS:**

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

LD50: Lethal Dose, 50 percent (Not relevant for classification)

LC50: Lethal concentration, 50 percent (Not relevant for classification)

**\*Data compared to the previous version altered.**

<b>Date Adopted</b>	<b>2017-03-21</b>
<b>REF 5118-8</b>	<b>Bordetella Pertussis IgG ELISA kit</b>

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