



DIAGNOSTIC AUTOMATION, INC.

21250 Califa Street, Suite 102 and 116, Woodland Hills, CA 91367

Tel: (818) 591-3030 Fax: (818) 591-8383

onestep@rapidtest.com

technicalsupport@rapidtest.com

www.rapidtest.com

MATERIAL SAFETY DATA SHEET

Bordetella Pertussis IgM ELISA kit

1. IDENTIFICATION OF THE PREPARATION AND COMPANY.

1.1. Identification of the product:

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

Product classification: In-vitro diagnostics

Product number: 5119-8

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.**

Address: 21250 Califa Street, Suite 102 and 116, Woodland Hills,
California 91367

Phone: (818) 591-3030 Fax: (818) 591-8383

E-mail: onestep@rapidtest.com

Website: <http://www.rapidtest.com>

Emergency Telephone number: Please contact the local hospitals.

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

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.

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

Group A

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

Hazard Pictograms: Void

Signal Word: Void

Hazard Statements: Void

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:

CAS No.:	7664-93-9
DESCRIPTION:	Sulfuric acid
EINECS:	231-639-5
INDEX NUMBER:	016-020-00-8
ELEMENTAL FORMULA:	H ₂ SO ₄
MOLAR MASS:	98.08
CONCENTRATION IN MIXTURE:	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. CO₂, 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

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

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

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

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.

Group B

Limit Values that Require Monitoring At Workplace:

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

DNEL Values (Sulphuric Acid):

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

PNEC Values (Sulphuric Acid)

PNEC	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: ≥ 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 ≥ 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)
General Information						
Appearance:						
Form	Fluid	Fluid	Fluid	Fluid	Fluid	Fluid
Colour:	Blue	Colourless	red	Colourless	Blue	Colourless
Odour:	Odourless	Odourless	Odourless	Odourless	Odourless	odourless
Odour Threshold	No information available	No information available	No information available	No information available	No information available	No information available
pH-Value at 25 °C:	6.0-7.4	3.3-3.8	6.2-7.2	6.2-7.2	6.2-7.4	~0.6
Change In Condition:						
Melting Point/range	No information available	No information available	No information available	No information available	No information available	No information available
Boiling Point/range	100 °C	No information available	100 °C	100 °C	100 °C	100 °C
Flash point:	No information available	No information available	No information available	No information available	No information available	No information available
Flammability (Solid, gaseous)	No information available	No information available	No information available	No information available	No information available	No information available
Ignition Temperature	No information available	No information available	No information available	No information available	No information available	No information available
Decomposition Temperature:	No information available	No information available	No information available	No information available	No information available	No information available
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	The mixture is not self-igniting
Danger of Explosion:	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
Explosion Limits:						
Lower:	No information available	No information available	No information available	No information available	No information available	No information available
Upper:	No information available	No information available	No information available	No information available	No information available	No information available
Oxidizing Properties	No information available	No information available	No information available	No information available	No information available	No information available
Vapour Pressure at 20°C:	No information available	No information available	No information available	No information available	No information available	23 hPa

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

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.

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.

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.

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:

Phone: (818) 591-3030

Fax: (818) 591-8383

E-mail: onestep@rapidtest.com

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 Labeling 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.**

Date Adopted	2017-03-21
REF 5119-8	Bordetella Pertussis IgM ELISA kit

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