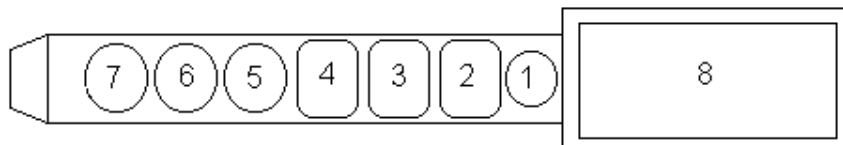


Chorus Legionella Urinary Antigen (REF 81301) is an immunoenzymatic method for the qualitative determination of Legionella pneumophila urinary antigen in human urine, using a disposable device applied on the Chorus and Chorus TRIO instruments. Each package contains 6 bags with 6 devices each (sufficient for 36 determinations of total).

Each kit consists of:

- Device:



Position 8: Space for application of bar code label

Position 7: Empty

Position 6: MICROPLATE WELL

Coated with highly purified anti-Legionella pneumophila monoclonal antibodies

Position 5: MICROPLATE WELL

Uncoated.

Position 4: TMB SUBSTRATE 0.40 ml

The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: Tetramethylbenzidine and H₂O₂ 0.01% stabilized in buffer.

Position 3: MONOCLONAL ANTIBODIES 0.35 ml

The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: anti-Legionella pneumophila antibodies labeled with Biotin in TRIS buffer.

Position 2: CONJUGATE 0.35 ml

The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.

For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.

Contents: Streptavidin solution labelled with horseradish peroxidase, in phosphate buffer containing phenol 0.05% and Bronidox 0.02%.

Position 1: EMPTY WELL

In which the operator must place the undiluted sample

- CALIBRATOR 0.350 ml
Inactivated Legionella pneumophila cells in phosphate buffer and preservative. Liquid, ready for use.
- POSITIVE CONTROL 0.850 ml
Inactivated Legionella pneumophila cells in phosphate buffer and preservative. Liquid, ready for use.

Both mixtures are not classified as dangerous according to Regulation 1272/2008/EC.

However, they contain substances classified as hazardous according to the Regulation and/or having occupational exposure limits for which it is required to develop of the material safety data sheet according to art. 31 of Regulation 1907/2006.

For these mixtures the material safety data sheet, prepared in accordance with EC regulations 1907/2006 and 453/2010, is available below.



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CALIBRATOR/POSITIVE CONTROL
CHORUS LEGIONELLA URINARY ANTIGEN
(According to Regulation (EC) No. 1907/2006 and 453/2010)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

1.1 IDENTIFICATION OF THE PRODUCT

Product name: CALIBRATOR/POSITIVE CONTROL
Product number: PF 81801-C1/81801-C2
Brand: DIESSE

1.2 IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Identified use: Professional use as laboratory reagent.
Calibrator: composed of Legionella pneumophila inactivated cells, necessary for the calibration of the instrument.
Positive Control: composed of Legionella pneumophila inactivated cells, is used to verify the correctness of the obtained results and for the subsequent validation of the test.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: DIESSE Diagnostica Senese SpA

<u>Registered office:</u> Via A. Solari 19, 20144 Milan, Italy Tel: +39 02 4859121 Fax: +39 02 48008530	<u>Production plant:</u> Via delle Rose, 10 –Loc. Tognazza 53035 Monteriggioni (SI), Italy Tel: +39 0577 319560/61 Fax: +39 0577 318763
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1.4 EMERGENCY TELEPHONE NUMBER

Emergency number: Centro Antiveleni, Ospedale Niguarda Ca' Granda - Milano
Tel: +39 02 66101029

Centro Antiveleni, Azienda Ospedaliera "S.G.Battista" – Molinette di Torino - Torino
Tel: +39 011 6637637

Centro Antiveleni – U.O. Tossicologia Medica, Azienda Ospedaliera Careggi – Firenze
Tel: +39 055 4277238

Centro Antiveleni, Policlinico A. Gemelli – Università Cattolica del Sacro Cuore - Roma
Tel: +39 06 3054343

Centro Antiveleni, Azienda Ospedaliera A. Cardarelli – Napoli
Tel: +39 081 7472870

web: http://www.salute.gov.it/servizio/documenti/centri_antiveleni.pdf

2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

Classification according to Regulation (EC) No. 1272/2008:

The mixture is not classified according to Regulation 1272/2008/EC.

However, they contain substances classified as hazardous according to the Regulation and/or having occupational exposure limits for which it is required to develop of the material safety data sheet according to art. 31 of Regulation 1907/2006.

Hazard statement:
None

2.2 LABEL ELEMENTS

Pictograms: None

Signal word: None

Hazard statement(s): None

Precautionary statement(s): None

2.3 OTHER HAZARDS:

None



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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES Not applicable

3.2 MIXTURES

International Chemical Identifier	Concentration	Classification EC Regulation 1272/2008	
Ethylene glycol			
Cas No 107-21-1			
CE No 203-473-3	14-18%	Acute Tox. 4	H302
Index No 603-027-00-1			
Reach No 01-2119456816-28-XXXX			
Sodium azide			
Cas No 26628-22-8		Acute Tox. 2 oral	H300
CE No 247-852-1	<0.1%	Aquatic Acute 1	H400
Index No 011-004-00-7		Aquatic Chronic 1	H410
Sostanza con limite di esposizione professionale			EUH032

The entire text of Hazard Statements is reported at Section 16 of the sheet.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General advice:	Move the person from the exposure to open air. Consult a physician immediately and show this Material Safety Datasheet.
Skin contact:	Wear off the contaminated clothes and wash with copious amounts of water.
Eye contact:	If present, remove immediately contact lenses (if present). Wash with plenty of water at least 15 minutes, keeping eyelids opened. Consult an oculist if the irritation persists.
Inhalation:	Consult a physician.
Ingestion:	Rinse mouth immediately and drink a copious amounts of water. Call a physician immediately. Do not cause vomiting.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS

No data available

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available

5. FIREFIGHTING MEASURES

5.1 EXTINGUISH MEDIA

Suitable extinguishing media: Use extinguishing measures (water, CO₂, foam, powder) that are appropriate to local circumstances and the surrounding environment

Not Suitable extinguishing media: None

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

If heated, the mixture may release combustible vapors which diffuse along floors.
The mixture is not flammable, however in case of fire may release irritating and/or toxic gases (CO₂, CO, NOx).

5.3 ADVICE FOR FIREFIGHTERS

In case of fire wear self-contained breathing apparatus. Avoid that fire extinguishing water contaminates surface water and/or groundwater.



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6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Keep people not involved in the intervention operations away. Avoid inhalation contact with vapors/aerosols. Ensure an adequate ventilation of the affected area.

Do not handle damaged containers or the leaked product before wearing appropriate protective outfit.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid the contamination of surface water, soil and the dispersion in the air. Do not let product enter into drains. Discharge into the environment must be avoided.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Contain the leakages with earth and sand. Collect the spilled material and store it in suitable containers for disposal. Use water only to remove residuals, to avoid the danger of spill of product into the sewers.

6.4 REFERENCE TO OTHER SECTIONS

For further information see section 8 and 13.

7. HANDLING AND STORAGE

7.1 PRECAUTION FOR SAFE HANDLING

Work in well ventilated areas and in the presence of ventilation systems or personal protective equipment. Do not inhale vapors or mists. Avoid contact with eyes and skin.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep at 2-8°C in a cool, well-ventilated area, away from heat sources and humidity. Close accurately the containers and keep them vertically avoiding the possibility of falls and leakage.

7.3 SPECIFIC END USE

None

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Applicable exposure limits:

Description	Type	TWA/8h		STEL/15min	
		mg/m ³	ppm	mg/m ³	ppm
Ethylene glycol*	D.Lgs 81/2008	52	20	104	40
Sodium Azide*	D.Lgs 81/2008	0.1		0.3	

*Note: Skin

Other information:

Ethylene glycol

Derived no effect level (IUCLID)

PNEC

Fresh water: 10 mg/L

Marine water: 1 mg/L

Intermittent release: 10 mg/L

STP 199.5 mg/L

Sediments (Fresh water): 20.9 mg/kg sediment dw

Soil: 1.53 mg/kg soil dw

DNEL (Workers)

Long-term exposure - systemic effects - dermal: 106 mg/kg bw/day

Long-term exposure - systemic effects - inhalation: 35 mg/m³

DNEL (Population)

Long-term exposure - systemic effects - dermal: 53 mg/kg bw/day

Long-term exposure - systemic effects - inhalation: 7 mg/m³

8.2 EXPOSURE CONTROLS

Work and handle according to the usual precautionary measures for handling chemicals.

Do not eat, drink or smoke while handling the product; wash hands thoroughly with



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soap and water before meals and after the work shift. Immediately remove all contaminated clothing.

Appropriate engineering controls:

Ensure an adequate ventilation of the working area and local ventilation system in case of exceedances of limit values for exposure.

Personal Protective Equipment:

The suggestions on the use of specific PPE are indicative. Their choice should be made according to the use of the product and the instructions given by the supplier of the device.

Hand protections:

Chemical-resistant gloves, compliant with EN 374.
Suitable material: nitrile rubber (thickness: 0.11 mm).
Gloves have to be checked by the user, before using.
Dispose the used gloves according to good laboratory practices and to law.
Clean and dry the hands after the use.

Eye protections:

Side Shields Safety Goggles compliant with EN 166

Body protections:

Work outfits

Respiratory protections:

In case of vapors/aerosol, the use a full face mask with combined filter type AP (EN 14387) may be need.

8.3 ENVIRONMENTAL EXPOSURE CONTROLS:

Do not discard residuals in the environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Liquid
Odor:	Characteristic
Odor threshold:	Not pertinent
pH:	No data available
Melting point/freezing point	197.6°C (Ethylene glycol)
Initial boiling point and boiling range	No data available
Flash point	111°C (Ethylene glycol)
Evaporation rate	Not pertinent
Flammability	Not pertinent
Upper/lower flammability or explosive limit	3.2-15,3 % v/v (Ethylene glycol)
Vapor pressure	0.053 hPa at 20°C (Ethylene glycol)
Vapor density	2.14 (Ethylene glycol)
Relative density	No data available
Water solubility	Soluble in water
Partition coefficient: n-octano/water	Log P _{o/w} : - 1.36 (Ethylene glycol)
Autoignition temperature	Not pertinent
Decomposition temperature	200-250°C (Ethylene glycol)
Viscosity	21 mPas (Ethylene glycol)
Explosive properties:	Not explosive
Oxidizing properties	No data available

9.2 OTHER SAFETY INFORMATION

None

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

In case of a strong heating, the product could form vapors, which are flammable if mixed with air.

10.2 CHEMICAL STABILITY

Stable under the recommended transport, handling and storage conditions



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10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Information about the contained substances:

Ethylene glycol

Risk of explosion in case of contact with aluminum and perchloric acid.
Risk of fire or formation of flammable gases in case of contact with chromium chloride, strong oxidizing agents, chlorate, potassium permanganate and peroxides.
Exothermic reactions with chlorosulfonic acid, sodium hydroxide and sulfuric acid are possible.

10.4 CONDITIONS TO AVOID

Avoid the strong heating of the mixture.
Sodium azide: in contact with acids could release highly toxic gases.

10.5 INCOMPATIBLE MATERIALS

Strong oxidizing and reducing agents.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

When heated or in case of fire, vapors potentially dangerous to health (boron hydroxyde, COx) may be produced.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

The product is harmful if swallowed.
The product can cause an allergic reaction in case of contact with skin.

Toxicological properties of the substances

Ethylene glycol

Acute toxicity:	No data available
Skin irritation/corrosion:	Results of tests performed using rabbits: Not corrosive; slight irritation of skin with reversible effects within 72h
Eye lesions/severe eye irritation:	Results of tests performed using rabbits: slightly irritating with completely reversible effects
Respiratory/skin sensitization:	Patch test results: Negative
Mutagenicity for germ cells:	Results of In vitro genotoxicity tests (Ames test with metabolic activation): Negative
Carcinogenicity:	No data available
Reproductive toxicity:	No data available
Toxicity for target organs (single and repeated exposures):	No data available
Hazards in case of inhalation:	No data available
Additional information:	No data available

12. ECOLOGICAL INFORMATION

12.1 TOXICITY

Use according to the good working practices, avoiding the disposal in the environment. In case the product reach waterways or sewers or contaminate soil or vegetation, inform the competent authorities.

Toxic properties of the substances

Ethylene glycol

Fishes (Oncorhynchus mykiss, 96h): CL50> 18500 mg/l
Invertebrates (Daphnia magna, 24h): EC50 74000 mg/l
Algae (Scenedesmus quadricauda, 7d): IC5>10000 mg/l

12.2 PERSISTENCE AND DEGRADABILITY

Ethylene glycol: readily biodegradable (OECD TG 301C)

12.3 BIOACCUMULATIVE POTENTIAL

No data available

12.4 MOBILITY IN SOIL

No data available



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12.5 RESULTS OF PBT AND VPVB ASSESSMENT

No data available

12.6 OTHER ADVERSE EFFECTS

No data available

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

The product and its containers should be considered special waste.
Their transport and disposal should be performed by authorized specialized companies according to the law.

14. TRANSPORT INFORMATION

Not hazardous good according to the transport regulations.

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Hazard classification and labeling under directives 1272/2008 (EC) and its subsequent amendments.

Legislative Decree 81/2008:

The use of this chemical entails the obligation of "Risk Assessment" by the employer in accordance with the provisions of the Decree April 9, 2008 n. 81 and subsequent amendments. Workers exposed to this chemical agent must not undergo health checks whether the results of the risk assessment show that, depending on the type and quantity of chemical agent and the method and frequency of exposure to this agent, there is only one "Low risk to the safety and irrelevant to the health" of the workers and the measures provided for in the same Decree are sufficient to reduce the risk

European Standard 1907/2006/EC:

Not applicable

Directive 96/82/EC (Seveso Directive):

Not applicable

15.2 CHEMICAL SAFETY ASSESSMENT

Not performed for the product

16. OTHER INFORMATION

This product has to be used for diagnostic use only by personnel who is qualified and trained on the hazards shown in this safety sheet.

Text of the hazard statements present at point 3

H300 Lethal if swallowed

H302 Harmful if swallowed

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

EUH 032 Contact with acids liberates very toxic gas

REFERENCES:

1. Direttiva 1999/45/CE e successive modifiche
2. Regolamento (CE) 1907/2006 del Parlamento Europeo (REACH) e s.m.i.
3. Regolamento (CE) 1272/2008 del Parlamento Europeo (CLP) e s.m.i
4. Regolamento (UE) 453/2010
5. ECHA European Chemicals Agency www.echa.europa.eu
6. The Merck Index.
7. Handling Chemical Safety
8. Niosh - Registry of Toxic Effects of Chemical Substances
9. INRS - Fiche Toxicologique



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