

Safety Data Sheet

According to 1907/2006/EC, Article 31 (REACH)

Version No. 1a

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY/ UNDERTAK-ING

1.1. Identification of the substance or preparationProduct name:Chloramphenicol ELISA**Catalogue Number:**DECAPE02

Components:

Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution

1.2. Use of the substance/preparation

Enzyme immunoassay for the quantitative determination of chloramphenicol in food and urine

1.3. Company / undertaking identification

Manufacturer/Supplier:	Demeditec Diagnostics GmbH Lise-Meitner-Str. 2
	24145 Kiel
	Germany
	Tel.: +49(0)431 / 71922-0
eMail-Adress of the qualified person:	info@demeditec.de

1.4. Emergency telephone

In case of further inquiry please contact the telephone number +49(0)431/71922-0 (technical service, business hours 8 a.m. to 4:30 p.m.).



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2. HAZARDS IDENTIFICATION

The components of the prepara	ation are classified according to dire	ctive 1999/45/EC as follows:
Classification:	Microtiter strips	Not classified
	Standards	Not classified
	Antibody solution	Not classified
	Enzyme conjugate	Not classified
	Washing buffer (10x concentrate)	Not classified
	Sample diluent	Not classified
	Substrate	Not classified
	Stop solution	Corrosive, C, R34
Health hazards:	Microtiter strips	Not applicable
	Standards	Not applicable
	Antibody solution	Not applicable
	Enzyme conjugate	Not applicable
	Washing buffer (10x concentrate)	Not applicable
	Sample diluent	Not applicable
	Substrate	Not applicable
	Stop solution	Causes burns

For detailed information to health effects and symptoms see section 11.

3. COMPOSITION / INFORMATION ON INGREDIENTS		
Substance / component:	Microtiter strips	Commodity
	Standards	Preparation
	Antibody solution	Preparation
	Enzyme conjugate	Preparation
	Washing buffer (10x concentrate)	Preparation
	Sample diluent	Preparation
	Substrate	Preparation
	Stop solution	Sulfuric acid (H_2SO_4), 0.5 M

Hazardous substance	Concentration	CAS No.	EC No.	Classification
Sulfuric acid	1-5%	7664-93-9	231-639-5	C, R35

See section 16 for the detailed text of the above stated r-phrases.

There are no ingredients contained in the preparation which are classified as harmful or polluting in the contained concentrations according to the actual state of knowledge of the manufacturer. The product is not hazardous in the sense of the directive 67/548/EC.



4. FIRST AID MEASURES

Inhalation:	Microtiter strips	
		ove person into fresh air. If not
	Antibody solution bre	eathing give artificial respiration. In
	, , , , , , , , , , , , , , , , , , , ,	se of severe disturbance consult a
	Washing buffer (10x concentrate) ∕ ph	ysician.
	Sample diluent	
	Substrate	
	Stop solution	
Ingestion:	Microtiter strips	
		NOT induce vomiting. Never give
		ything by mouth to an unconscious
		rson. In case of severe disturbance
		nsult a physician.
	Sample diluent	
	Substrate	
	Stop solution	
Skin contact:		nse skin with plenty of water. Re-
		ove contaminated clothes and pro-
	,	tive gloves. Wash clothes thoroughly
	, , , , , , , , , , , , , , , , , , , ,	fore reuse. Clean shoes. In case of
		vere disturbance consult a physician.
	Sample diluent	
	Substrate	
Free contracts	Stop solution	
Eye contact:	Microtiter strips	
		nse thoroughly with plenty of water
		at least 15 minutes. Remove con-
	, , , , , , , , , , , , , , , , , , , ,	t lenses. In case of severe distur-
		nce consult a physician.
	Sample diluent Substrate	
	Stop solution	
Protection of first aider:	Microtiter strips No	ot applicable
	Standards No	ot applicable
	Antibody solution No	ot applicable
	Enzyme conjugate No	ot applicable
	Washing buffer (10x concentrate) No	ot applicable
	Sample diluent No	ot applicable
		ot applicable
		o not take any actions which are con-
		cted to any personal risk or which
		ere not adequately trained. If vapors
		e suspected, wear appropriate air-pu-
		ying respirator. For first-aid providing
		rsons there exists a possible risk due
		mouth-to-mouth resuscitation. Re-
		ove contaminated clothing. Wear pro-
		ctive gloves.
Advice for physicians:	No special treatment. Treat symptoma	
	inhalation of larger amounts consult to	oxicologist.
Special treatment:	No data available.	
For detailed information to	health impacts and symptoms see see	ction 11.



5. **FIRE-FIGHTING MEASURES**

Not suitable extinguishing media:	Microtiter strips Standards		Not applicable Not applicable
	Antibody solutio	n	Not applicable
	Enzyme conjuga		Not applicable
	Washing buffer	(10x concentrate)Not applicable
	Sample diluent		Not applicable
	Substrate		Not applicable
	Stop solution		Do not use water jet.
suitable extinguishing media:	Consider adjace	ent fires when ch	oosing the extinguishing medium.
Dangerous combustion products:		le.	
Special protective equipment for fi	re-fighters:		ate personal protective equipment. operated full-face respirator.

6. ACCIDENTAL RELEASE MEASURES		
Personal Precautions:	Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution	Do not take any actions which are con- nected to any personal risk or which were not adequately trained. Evacuate surrounding. Prohibit access for not protected persons. Do not touch or tread spilled substance. Avoid inhala- tion of vapors or mist. Care for suffi- cient ventilation. If ventilation is insuffi- cient, wear respirator. Wear adequate personal protective equipment (see section 8).
Environmental Precautions:	Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution	Avoid spreading and drain-off of spilled material as well as contact with soil, watercourses, drains or canalization. Contact responsible department, if
Methods for cleaning:	Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution	Sweep material and dispose in an ap- propriate labeled container. Dispose via an approved waste disposal company. Eliminate leakage. Remove container from contaminated area. Swab with a cloth or adsorb with an inert dry ma- terial and dispose in an appropriate labeled container. Dispose via an ap- proved waste disposal company.



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7. HANDLING AND STO	RAGE
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Handling:	Microtiter strips Standards	
	Antibody solution	After handling wash hands thoroughly.
	Enzyme conjugate	<u>_</u>
	Washing buffer (10x concentrate)	
	Sample diluent	
	Substrate	
	Stop solution	Do not ingest. Avoid contact with eyes, skin or clothes. Use only with sufficient ventilation. Do not inhale vapor or mist.
Storago:	Store at 2.8°C. Protect from direct	After handling wash hands thoroughly. sun light. Store only in original contain-
Storage:		d. Keep containers closed until usage. Af-
	•	again tightly. Do not store in unlabeled
	containers. Consider local regulation	
Specific use:		ne instruction manual for the determina-
	0	s agents. Do not use reagents for other
	purposes.	5
8. EXPOSURE CONTROLS	S / PERSONAL PROTECTION	
8. EXPOSURE CONTROLS 8.1. Exposure limit values	S / PERSONAL PROTECTION Microtiter strips	Not applicable
	S / PERSONAL PROTECTION Microtiter strips Standards	Not applicable
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution	Not applicable Not applicable
	5 / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate	Not applicable Not applicable Not applicable
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate)	Not applicable Not applicable Not applicable Not applicable
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent	Not applicable Not applicable Not applicable Not applicable Not applicable
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent	Not applicable Not applicable Not applicable Not applicable Not applicable
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution Substance	Not applicable Not applicable Not applicable Not applicable Not applicable See table Sulfuric acid
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution Substance Type of exposure limit	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable See table Sulfuric acid Threshold limit value (Germany 2009)
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution Substance	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable See table Sulfuric acid Threshold limit value (Germany 2009) 0.1 mg/m ³ determined as respirable
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution Substance Type of exposure limit Exposure limit	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable See table Sulfuric acid Threshold limit value (Germany 2009) 0.1 mg/m ³ determined as respirable aerosol fraction
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution Substance Type of exposure limit	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable See table Sulfuric acid Threshold limit value (Germany 2009) 0.1 mg/m ³ determined as respirable aerosol fraction 0.2 mg/m ³ determined as respirable
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution Substance Type of exposure limit Exposure limit Momentary value	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable See table Sulfuric acid Threshold limit value (Germany 2009) 0.1 mg/m ³ determined as respirable aerosol fraction 0.2 mg/m ³ determined as respirable aerosol fraction
	S / PERSONAL PROTECTION Microtiter strips Standards Antibody solution Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution Substance Type of exposure limit Exposure limit	Not applicable Not applicable Not applicable Not applicable Not applicable Not applicable See table Sulfuric acid Threshold limit value (Germany 2009) 0.1 mg/m ³ determined as respirable aerosol fraction 0.2 mg/m ³ determined as respirable



8.2. Exposure controls			
Limitation of exposure in the	e working environment: No special ventilation procedures. Common ventila- tion should be sufficient to limit exposure of the employees towards air pol- lutants. Optionally use process chambers, local exhaust fans or other tech- nical equipment to keep exposition under recommended or mandatory lim- its.		
Hygienic measures:	After handling of chemical products as well as before eating, smoking or visit of a lavatory wash hands, forearms and optionally face thoroughly. Wash contaminated clothes before re-use. Ensure that close to the work environment eye wash stations and safety showers are available.		
Respiratory protection:	While handling according to the intended use no respiratory protection is necessary.		
Hand protection:	Wear chemical resistant impenetrable gloves according to the specifications of directive 89/686/EC and the resulting standard EN 374. Time of penetration of the glove material: permeation level > 6.		
Eye protection:	To avoid exposition against liquid spills, mist, gases or dust wear safety goggles with side protection according to the specifications of directive 89/686/EC and the resulting standard EN166.		
Body protection:	Wear closed lab coat.		
Monitoring of exposure in the working environment: For methods of monitoring the respiratory exposition			
	against chemical substances see the European standard EN 689.		
Limitation and monitoring of	f environmental exposure: Monitor the emission of ventilation and process		
	equipment for ensuring the compliance with the requirements of environ- ment protection laws. In case of exceeding threshold values install exhaust air washers, filters or other appropriate technical equipment.		

PHYSICAL AND CHEMICAL PROPERTIES 9.

9.1. General information		
Physical state:	Microtiter strips	plastic plate
	Standards	liquid
	Antibody solution	liquid
	Enzyme conjugate	liquid
	Washing buffer (10x concentrate)	liquid
	Sample diluent	liquid
	Substrate	liquid
	Stop solution	liquid
Color:	Microtiter strips	white/clear
	Standards	blue
	Antibody solution	blue
	Enzyme conjugate	red
	Washing buffer (10x concentrate)	clear
	Sample diluent	blue
	Substrate	clear
	Stop solution	clear



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9.2 Important health safety	and environmental information p	ρΗ.
	Microtiter strips	Not applicable
	Standards	6-8
	Antibody solution	6-8
		6-8
	Enzyme conjugate	
	Washing buffer (10x concentrate)	
	Sample diluent	6-8
	Substrate	3-4
	Stop solution	<1
Boiling point:	Microtiter strips	Not applicable
	Standards	
	Antibody solution	
	Enzyme conjugate	Lowest known value (water):
	Washing buffer (10x concentrate)	≻100°C/212°F
	Sample diluent	
	Substrate	
	Stop solution)
Melting point:	Microtiter strips	Not applicable
01	Standards)
	Antibody solution	
	Enzyme conjugate	May melt at 0°C/32°F
	Washing buffer (10x concentrate)	
	Sample diluent	ingredient water.
	Substrate	
	Stop solution -)
Solubility:	Microtiter strips	Not applicable
Coldonity	Standards	
	Antibody solution	
	Enzyme conjugate	Complete solubility in cold and hot water
	Washing buffer (10x concentrate)	
	Sample diluent	(`
	Substrate	
	Stop solution)
Vapor pressure:	Microtiter strips	Not applicable
	Standards	
	Antibody solution	22.4 mbox at 20° C/68°E
	Enzyme conjugate	23.4 mbar at 20°C/68°F
	,	This specification is based on the
	Sample diluent	ingredient water.
	Substrate	
	Stop solution	
No available data:		nition temperatures, viscosity, oxidizing
	properties, density, partition coeffi	icient (octanoi/water).
10. STABILITY AND REACT	Ίνιτγ	
10.1. Conditions to avoid	N 41 111 111 -	
	Microtiter strips	
	Standards	Components of the product are stable.
	Antibody solution	Under the specified storage conditions
	Enzyme conjugate	ho degradation or polymerization will
	M (applied buffer (10x concentrate)	

Thermal stress.

Washing buffer (10x concentrate) | occur.

Sample diluent Substrate Stop solution



10.2. Materials to avoid10.3. Dangerous decomp	Under the specified storage and position products are formed. In	When handled according to the intended use no hazardous reactions are to be expected. Strong bases. I handling conditions no dangerous decom- the case of fire, dangerous decomposition oxides, sulfuric oxides) may occur.			
11. TOXICOLOGICAL INFO	ORMATION				
Inhalation:	Microtiter strips				
innalation.	Standards				
	Antibody solution	No health effects known.			
	Enzyme conjugate				
	Washing buffer (10x concentrate	e)			
	Sample diluent				
	Substrate)			
	Stop solution	May cause irritation of the respiratory system.			
Ingestion:	Microtiter strips				
-	Standards				
	Antibody solution	No health effects known.			
	Enzyme conjugate	>			
	Washing buffer (10x concentrate	e)			
	Sample diluent				
	Substrate				
	Stop solution	May cause irritations in mouth or throat.			
Skin contact:	Microtiter strips				
	Standards	No health effects known.			
	Antibody solution Enzyme conjugate				
	Washing buffer (10x concentrate	e) (
	Sample diluent				
	Substrate				
	Stop solution	May cause irritation of the skin.			
Eye contact:	Microtiter strips				
	Standards				
	Antibody solution	No health effects known.			
	Enzyme conjugate	>			
	Washing buffer (10x concentrate	e)			
	Sample diluent				
	Substrate				
	Stop solution	May cause irritation of the eyes.			
The following information is h	ased on sulfuric acid as ingredient	of the stop solution:			
	LD50:	2140 mg/kg (rat)			
	Sensitization:	No sensitizing effects known.			
Further information of the cor					
Further information of the components to chronic toxicity, carcinogenicity, mutagenicity, teratogenicity or reproductive toxicity is not available.					



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12. ECOLOGICAL INFORMATION

The following information is based on sulfuric acid as ingredient of the stop solution. For all other components no data are available.

Aquatic toxicity: Harmful effects on water organisms due to pH shift. Quantitative data to the ecological effects of the product are not available.

Water hazard class: WGK 1 (according to annex 2 of the German administrative rule for substances harmful to water): weakly harmful to water.

13. DISPOSAL CONSIDERATIONS

Waste disposal methods:	: Consider all national environmental protection requirements and waste disposal laws as well as local rules. Avoid spreading of spilled material through contact	
Hazardous waste:	with soil, water courses, drains or canalization. According to our current knowledge no hazardous waste in the sense of the European directive 91/689/EC.	

14. TRANSPORT INFORMATION

This product is not subject to the rules of the following traffic systems: Street traffic: ADR (directive 94/55/EC) Rail traffic: RID (directive 96/49/EC) Sea traffic: IMDG Air traffic: ICAO/IATA

15. REGULATORY INFORMATION

Identification according to European directives: The classification and identification was performed according to the European directives 67/548/EC and 1999/45/EC (including amendments) and consider the intended use of the product. A Chemical Safety Assessment was not conducted for substances included in this preparation.

	101 30031	ances included in this pre		
R-phrases:	Microtite	r strips		
	Standard	ls		
	Antibody	solution	This product is not classified according	
	Enzyme	conjugate	to European laws.	
	Washing	buffer (10x concentrate)		
	Sample	diluent		
	Substrat)	
	Stop sol	ution	R34: Causes burns.	
S-phrases:	Microtite			
-	Standard	•		
		solution	S 36: Wear suitable protective clothing.	
		conjugate		
		buffer (10x concentrate)		
	Sample	,		
	Substrat)	
	Stop sol		S26: In case of contact with eyes, rinse immediate	lv with
	otop oon		plenty of water and seek medical advice.	i y man
			S36/37/39: Wear suitable protective clothing, glove	es and
			eye/face protection.	
			S45: In case of accident or if you feel unwell seek	medical
			advice immediately (show the label where possible	
European inv	entory:	Sulfuric acid as ingredie		<i>.</i> ,.
National rules:		Sulfuric acid as ingredient of the stop solution not listed. German administrative rule for substances harmful to water (VwVwS): WGK 1 (ac-		
		cording to annex 2): weakly harmful to water.		
	German regulation for industrial safety (BetrSichV): no classification.			
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16. OTHER INFORMATION

Microtiter strips	<u>٢</u>	
Calibrators		
Enzyme conjugate	Not applicable.	
Washing buffer (10x concentrate)		
Sample diluent		
Substrate	J	
Stop solution	R34: Causes burns.	
	R35: causes severe burns.	
Version 1a: 2010-12-08 (creation	n 1a: 2010-12-08 (creation and release)	
The information is based on our present knowledge, but is not a guaranty of special product properties and establishes no legal relationship.		
	Enzyme conjugate Washing buffer (10x concentrate) Sample diluent Substrate Stop solution Version 1a: 2010-12-08 (creation The information is based on our p	