

KLINIK FÜR VÖGEL, REPTILIEN,
AMPHIBIEN UND FISCHE
JUSTUS-LIEBIG-UNIVERSITÄT GIESSEN
Director: Prof. Dr. E. F. Kaleta

D-35392 GIESSEN, Monday, 05 December 2005
Frankfurter Strasse 91-93
Telefon 0641/99-38430
Telefax 0641/9938439
Erhard.f.kaleta@vetmed.uni-giessen.de



Klinik f. Vögel, Rept., Amph. u. Fische; Frankfurter Str. 91-93, D-35392 Gießen

TEST REPORT
EN 14675, VIRUCIDAL ACTIVITY
(obligatory conditions using avian influenza A virus)

Client: RMP GmbH & Co. KG, Hagenring 20, 72119 Altingen

Disinfectant-sample: 25 Tablets each 2.78 g

Name of the product: DISIFIN® ANIMAL Desinfektions Tabs

Batch number: 07112005

Manufacturer: RMP GmbH & Co. KG

Storage conditions: Room temperature, darkness, in the original pack

Appearance of the product: White, round tablets

Active substances and their concentrations: 90-95 % Sodium-p-toluolsulfonchloramide

Product diluent recommended by the manufacturer for use: Water

Period of testing: 22/11/2005 – 05/12/2005

Date of delivery of the product: 21/11/2005

Dates of tests: See tables 1-5 (attached)

Experimental conditions:

Product diluent: Hard water

Concentrations of the product tested: See tables 1-5 (attached)

Obligatory conditions:

Test-organism: Influenza A/Carduelis/Germany/72 (H7N1), agent of a highly pathogenic avian influenza (HPAI)

Test temperature: 10 ± 1 °C

Contact time: 30 ± 1 min

Interfering substance: 3 g/l bovine albumin (low level organic soiling), 10 g/l yeast extract + 10 g/l bovine albumin (high level organic soiling);

Incubation temperature: 37 °C.

Special remarks regarding the results: No precipitate during the test procedure.

Conclusion:

For the product DISIFIN ANIMAL Desinfektions Tabs (batch 07112005), the virucidal concentration for disinfection of influenza viruses determined according to the EN 14675 standard (obligatory conditions) under without, low level and high-level soiling is:

0,05 % (w/v) of active compound (Sodium-p-toluolsulfonchloramide)

Giessen, 05/12/2005



E. F . Kaleta, Prof. Dr. med. vet.
Director



A. Yilmaz, Dr. med. vet.

Table 1: Virucidal activity of DISIFIN ANIMAL against avian influenza A virus (A/carduelis/Germany/72, H7N1) in suspension without organic soiling. Test temperature: 10 ± 1 °C. Contact time: 30 ± 1 min.

Concentration	Set	Dilution (10^x)								Virus titre (TCID ₅₀ /ml)	Titre reduction in log ₁₀
		2	3	4	5	6	7	8	9		
Negative control	1	4444 4444	4444 4444	4444 4444	4444 4444	4444 0444	4000 0400	0000 0000	0000 0000	7.6	
	2	4444 4444	4444 4444	4444 4444	4444 4444	4404 0044	0004 4400	0000 0000	0000 0000	7.5	-
0.05 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤ 2.5	≥ 5.1
	2	0000 0000	0000 0000	0000 0000	0000 0000	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	≤ 2.5	≥ 5.0
0.1 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤ 2.5	≥ 5.1
	2	0000 0000	0000 0000	0000 0000	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	≤ 2.5	≥ 5.0
0.25 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤ 2.5	≥ 5.1
	2	0000 0000	0000 0000	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	≤ 2.5	≥ 5.0
0.5 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤ 2.5	≥ 5.1
	2	0000 0000	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	≤ 2.5	≥ 5.0

0 = no CPE

1 = cells with CPE

2 = ~50 % of cells with CPE

3 = most of cells with CPE

4 = all of cells with CPE

n. t.: not tested

Table 2: Virucidal activity of DISIFIN ANIMAL against avian influenza A virus (A/carduelis/Germany/72, H7N1) in suspension with **low level organic soiling**. Test temperature: 10 ± 1 °C. Contact time: 30 ± 1 min.

Concentration	Set	Dilution (10 ¹)								Virus titre (TCID ₅₀ /ml)	Titre reduction in log ₁₀	
		2	3	4	5	6	7	8	9			
Negative control	1	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4000	0040 0000	0000 0000	0000 0000	7.6	-
	2	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4440 4000	0004 0000	0000 0000	0000 0000	7.6	-
0.05 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤2.5	≥5.1
	2	0000 0000	0000 0000	0000 0000	0000 0000	n. t.	n. t.	n. t.	n. t.	n. t.	≤2.5	≥5.1
0.1 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤2.5	≥5.1
	2	0000 0000	0000 0000	0000 0000	n. t.	n. t.	n. t.	n. t.	n. t.	n. t.	≤2.5	≥5.1
0.25 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤2.5	≥5.1
	2	0000 0000	0000 0000	n. t.	n. t.	n. t.	n. t.	n. t.	n. t.	n. t.	≤2.5	≥5.1
0.5 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤2.5	≥5.1
	2	0000 0000	n. t.	n. t.	n. t.	n. t.	n. t.	n. t.	n. t.	n. t.	≤2.5	≥5.1

0 = no CPE

1 = cells with CPE

2 = ~50 % of cells with CPE

3 = most of cells with CPE

4 = all of cells with CPE

n. t.: not tested

Table 3: Virucidal activity of DISIFIN ANIMAL against avian influenza A virus (A/carduelis/Germany/72, H7N1) in suspension with **high level organic soiling**. Test temperature: 10 ± 1 °C. Contact time: 30 ± 1 min.

Concentration	Set	Dilution (10 ^{-x})								Virus titre (TCID ₅₀ /ml)	Titre reduction in log ₁₀
		2	3	4	5	6	7	8	9		
Negative control	1	4444 4444	4444 4444	4444 4444	4444 4444	4444 4440	0000 0000	0000 0000	0000 0000	7.5	-
	2	4444 4444	4444 4444	4444 4444	4444 4444	4444 0044	0400 4000	0000 0000	0000 0000	7.5	-
0.05 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤2.5	≥5.0
	2	0000 0000	0000 0000	0000 0000	0000 0000	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	≤2.5	≥5.0
0.1 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤2.5	≥5.0
	2	0000 0000	0000 0000	0000 0000	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	≤2.5	≥5.0
0.25 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤2.5	≥5.0
	2	0000 0000	0000 0000	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	≤2.5	≥5.0
0.5 %	1	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	≤2.5	≥5.0
	2	0000 0000	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	n. t. n. t.	≤2.5	≥5.0

0 = no CPE

1 = cells with CPE

2 = ~50 % of cells with CPE

3 = most of cells with CPE

4 = all of cells with CPE

n. t.: not tested

Table 4: Results of qualitative cytotoxicity tests in CEF cultures according Annex B.1a

Disinfectant	Organic soiling	Disinfectant concentration in reaction mixture	Toxicity of different dilutions		
			10 ⁻²	10 ⁻³	10 ⁻⁴
DISIFIN ANIMAL	without	0.05 %	-	-	-
		0.1 %	-	-	-
		0.25 %	-	-	-
		0.5 %	-	-	-
	low level	0.05 %	-	-	-
		0.1 %	-	-	-
		0.25 %	-	-	-
		0.5 %	-	-	-
	high level	0.05 %	-	-	-
		0.1 %	-	-	-
		0.25 %	-	-	-
		0.5 %	-	-	-

+ toxic
- not toxic

Table 5: Results of quantitative cytotoxicity tests in CEF cultures according Annex B.1b

Disinfectant	Concentration	Dilution (10 ¹)	Virus titre (TCID ₅₀ /ml)		
			Without soiling	Low level soiling	High level soiling
DISIFIN ANIMAL	0.05 %	2	7.0	7.3	7.1
	0.1 %	2	7.1	7.0	7.1
	0.25 %	2	7.1	7.0	7.0
	0.5 %	2	7.3	7.1	7.1

Control 1: 7.0 TCID₅₀/ml

Control 2: 7.1 TCID₅₀/ml