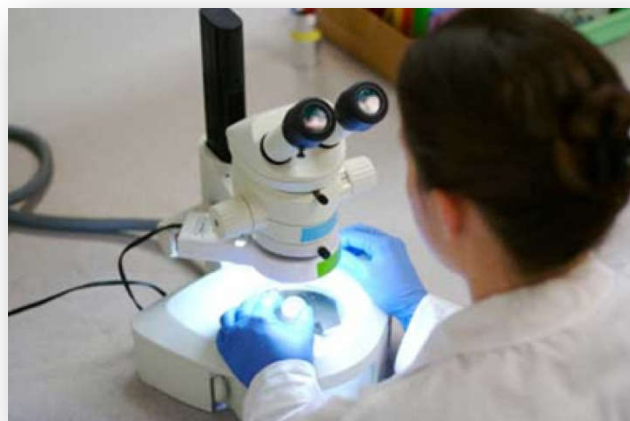




Evans Vanodine International plc

G L O B A L H Y G I E N E S O L U T I O N S

GPC 8



MICROBIOLOGICAL PROFILE

GPC 8 MICROBIOLOGICAL PROFILE

	<u>CONTENTS</u>	<u>PAGE</u>
	INTRODUCTION	3
1	National Approvals	4
	EFFECTIVE DILUTIONS FOR	
	Avian pathogens	5
	Bovine pathogens	6
	Canine pathogens	6
	Porcine pathogens	7 – 8
	Human pathogens	9
	Pathogenic fungi	9
	THE EFFECT OF CONTACT TIME AND TEMPERATURE ON BACTERICIDAL ACTIVITY	10
	APPENDIX I	
	Test method/Test laboratory references	11 - 13

GPC 8 MICROBIOLOGICAL PROFILE

INTRODUCTION

GPC8 is a powerful glutaraldehyde based general-purpose disinfectant and has a broad spectrum of activity. It is bactericidal, fungicidal and virucidal and therefore offers protection from a wide range of disease causing (pathogenic) microorganisms.

GPC8 has been tested against a wide range of microorganisms including field isolates and has proved effective even under adverse conditions e.g. the presence of heavy organic soiling and low temperatures.

GPC8 can be used wherever there is a risk of infection so is recommended for use in all types of livestock housing including calf pens, lambing pens, broiler houses. Housing and associated equipment for cattle, pigs, poultry and sheep (during lambing) can harbour large numbers of harmful micro-organisms. In order to reduce the numbers of these harmful micro-organisms, it is necessary to carry out thorough cleaning and disinfection.

GPC8 is recommended, as part of effective cleaning and disinfection (hygiene) programmes developed to meet the needs of intensive livestock production.

The use of **GPC8** as part of a hygiene programme can help to prevent infection, reducing financial losses due to high mortality rates, poor feed conversion, low weights and medication costs.

Results are presented in tables following with effective dilution rates expressed as one part of **GPC8** in total volume of solution (1:x). The test methods used are referred to in the tables and details are given in Appendix 1. References 1 and 2 are for the European Standards for bactericidal and fungicidal activity of disinfectants used in the veterinary area and are carried out under standard conditions (unless specifically noted) of 30 minutes contact time, 10°C and under high level soiling.

PLEASE REFER TO PRODUCT LABEL FOR HOW TO USE AND FOR ALL RECOMMENDED USE DILUTION RATES

GPC 8 MICROBIOLOGICAL PROFILE

NATIONAL APPROVALS

GPC8 is approved, by Defra, for disinfection of inanimate surfaces where an approved product is required to be used under the control legislation for the following specific disease orders:

ORDER	APPROVED DILUTION RATES
Foot and Mouth	1:80
Diseases of Poultry Order and the Avian Influenza and Influenza of Avian Origin in Mammals	1:50
General	1:45

Approved dilution rates are determined by testing at government laboratory facilities.

This approval is granted under the Diseases of Animals (Approved Disinfectants) Orders made by the Secretary of State for Environment, Food and Rural Affairs in England, Scottish Ministers in Scotland and Welsh Ministers in Wales.

For confirmation of continuing approval refer to the Defra list of approved disinfectants at <http://disinfectants.defra.gov.uk>.

GPC8 is also approved under the Diseases of Animals (Approved Disinfectants) Order in Northern Ireland and in Ireland as a disinfectant for the purposes of the Diseases of Animal Act, 1966 and Orders made thereunder.

GPC 8 MICROBIOLOGICAL PROFILE

EFFECTIVENESS OF GPC8 AGAINST AVIAN PATHOGENIC BACTERIA AND VIRUSES

BACTERIA	DISEASE	BACTERICIDAL DILUTION	Test Method / Laboratory Reference
<i>Enterococcus faecalis</i>	Enterococcal infection	1:800	1a
<i>Escherichia coli</i>	Colisepticaemia in chickens, particularly broilers	1:200	
<i>Pasteurella multocida</i>	Fowl cholera and pasteurellosis	1:400	
<i>Proteus vulgaris</i>	Yolk sac infection in poultry	1:250	
<i>Salmonella arizonae</i>	Salmonellosis	1:200	
<i>Salmonella gallinarum</i>	Fowl typhoid	1:100	
<i>Salmonella pullorum</i>	Pullorum disease (bacillary white diarrhoea)	1:200	
<i>Salmonella typhimurium</i>	Salmonellosis	1:400	
<i>Staphylococcus aureus</i>	Arthritis, bumblefoot and septicaemia	1:500	
VIRUS	DISEASE	VIRUCIDAL DILUTION	Test Method / Laboratory Reference
Avian adenovirus	Egg Drop Syndrome	1:100	11
Avian influenza virus Taiwan strain H6N1	Avian Influenza	1:220	9
Avian influenza virus H5N3	Avian Influenza	1:220	9
Avian influenza re-assortant virus H3N2	Avian Influenza	1:200	12a
Infectious Bronchitis virus	Infectious Bronchitis	1:100	7
Infectious Bursal Disease virus	Infectious Bursal Disease (Gumboro)	1:100	5
Infectious Laryngotracheitis virus	Infectious Laryngotracheitis	1:400	10
Marek's disease virus	Marek's Disease	1:200	13
Newcastle Disease virus	Newcastle Disease (Notifiable Disease)	1:50	DEFRA

GPC 8 MICROBIOLOGICAL PROFILE

EFFECTIVENESS OF GPC8 AGAINST BOVINE PATHOGENIC BACTERIA AND VIRUSES

BACTERIA	DISEASE	BACTERICIDAL DILUTION	Test Method / Laboratory Reference
<i>Escherichia coli</i>	Mastitis in dairy cattle and colibacilliosis in calves	1:200	1a
<i>Campylobacter jejuni</i>	Found in the intestines of cattle causes enteritis in man	1:1000	
<i>Corynebacterium pseudotuberculosis</i>	Skin lesions	1:100	
<i>Klebsiella pneumoniae</i>	Mastitis in dairy cattle	1:200	
<i>Leptospira interrogans</i>	Pomona or Hardjo infection resulting in abortion and loss of milk production in adult cattle:- Zoonosis	1:200	3
<i>Pseudomonas aeruginosa</i>	Mastitis in dairy cattle	1:50	1a
<i>Staphylococcus aureus</i>	Mastitis in dairy cattle	1:500	
VIRUS	DISEASE	VIRUCIDAL DILUTION	Test Method / Laboratory Reference
Bovine Viral Diarrhoea virus (BVD)	Mucosal disease. Acute infections may cause transient diarrhoea or pneumonia, high mortality rates, abortions and still births	1:25	14
Bovine enterovirus	Reproductive, gastrointestinal and respiratory disease	1:100	14
Foot and Mouth Disease Virus	Foot and Mouth (Notifiable Disease)	1:80	DEFRA

EFFECTIVENESS OF GPC8 AGAINST CANINE PATHOGENS

VIRUS	DISEASE	VIRUCIDAL DILUTION	Test Method / Laboratory Reference
Canine Distemper virus	Distemper	1:150	14

GPC 8 MICROBIOLOGICAL PROFILE

EFFECTIVENESS OF GPC8 AGAINST PORCINE PATHOGENIC BACTERIA

BACTERIA	DISEASE	BACTERICIDAL DILUTION	Test Method / Laboratory Reference
<i>Actinobacillus pleuropneumoniae</i> (App) Field isolate	Pleuropneumoniae, respiratory disease	1:100	15
<i>Bordetella bronchiseptica</i>	Atrophic rhinitis	1:200	1a
<i>Bordetella bronchiseptica</i> Field isolate	Atrophic rhinitis	1:100	15
<i>Brachyspira hyodysenteriae</i> Field isolate	Swine dysentery	1:200	15
<i>Enterococcus faecalis</i>	Watery diarrhoea in piglets	1:800	1a
<i>Enterococcus hirae</i>	Watery diarrhoea in piglets	1:1000	
<i>Escherichia coli</i>	Bowel odema, colibacillosis	1:200	
<i>Haemophila parasuis</i> (Hps) Field isolate	Glässers disease	1:100	15
<i>Mycoplasma hyopneumoniae</i>	Enzootic pneumonia	1:64000 Bacteriostatic dilution	4
<i>Pasteurella multocida</i>	Pasteurellosis.	1:400	1a
<i>Pseudomonas aeruginosa</i>	Cystitis and pyelonephritis	1:50	
<i>Salmonella cholerasuis</i>	Salmonellosis	1:45	DEFRA
<i>Salmonella enteritidis</i>	Salmonellosis	1:200	1a
<i>Staphylococcus aureus</i>	Mastitis	1:500	
<i>Streptococcus suis</i>	Pneumonia	1:1000	
<i>Streptococcus suis</i> Field isolate	Meningitis	1:400	15

GPC 8 MICROBIOLOGICAL PROFILE

EFFECTIVENESS OF GPC8 AGAINST PORCINE PATHOGENIC VIRUSES

VIRUS	DISEASE	VIRUCIDAL DILUTION	Test Method / Laboratory Reference
African Swine Fever virus	African Swine Fever	1:50	11
Aujesky's virus	Aujesky's Disease	1:250	5
Classical Swine Fever virus	Swine Fever (Hog Cholera)	1:100	5
Porcine Circovirus Type 2	Post Weaning Multisystemic Wasting Syndrome (PMWS) and Porcine Dermatitis and Nephropathy Syndrome (PDNS)	1:100*	13
Foot and Mouth Disease virus	Foot and Mouth (Notifiable disease)	1:80	DEFRA
Parvo virus	Parvo disease	1:200	6
Porcine Influenza A (H1N1)	Influenza	1:400	14
Porcine Rotavirus	Epidemic Diarrhoea	1:200**	10
PRRS Virus	Porcine Reproductive and Respiratory Syndrome (Blue Ear Disease)	1:200	6
TGE Virus	Transmissible gastro-enteritis	1:200	12b

* GPC8 passed the virucidal effectiveness test according to the US EPA regulatory agencies as a greater than 3log₁₀ reduction was demonstrated.

**3 log₁₀ reduction. In general, the accepted criteria of virucidal efficacy is a 4 log₁₀ reduction. Reductions of 2 to 3 log₁₀ point to moderate activity. However, virus of sufficiently high titre could not be obtained with the rotavirus strain to achieve the required net infectivity reduction over the cytotoxic background. In practical terms it is more than likely that GPC8 would have caused a 4 log₁₀ reduction if the virus had produced cytopathic effects at a dilution of 10⁻⁶.

GPC 8 MICROBIOLOGICAL PROFILE

EFFECTIVENESS OF GPC8 AGAINST HUMAN PATHOGENIC BACTERIA AND VIRUSES

BACTERIA	DISEASE	BACTERICIDAL DILUTION	Test Method / Laboratory Reference
<i>Escherichia coli</i> 0157	Food poisoning, which can result in enteritis and haemolytic uraemic syndrome (characterised by renal failure)	1:200	1a
<i>Campylobacter jejuni</i>	Enterocolitis, a major cause of diarrhoea	1:1000	
<i>Pseudomonas aeruginosa</i>	Nosocomial infections (hospital acquired) wound infections	1:50	
<i>Salmonella enteritidis</i>	Food poisoning (linked with poultry) resulting in gastro-enteritis	1:200	
<i>Salmonella typhimurium</i>	Food poisoning (linked with cattle) resulting in gastro-enteritis	1:400	
<i>Shigella sonnei</i>	Dysentery	1:200	
<i>Staphylococcus aureus</i>	Boils, wound infections	1:500	
<i>Streptococcus pyogenes</i>	Throat infections	1:800	
VIRUS	DISEASE	VIRUCIDAL DILUTION	
Hepatitis B (HBV)	Hepatitis B	1:30	8a
Hepatitis C (HCV)	Hepatitis C	1:30	8b
Human Immunodeficiency type 1 (HIV)	AIDS	1:60	8c

EFFECTIVENESS OF GPC8 AGAINST PATHOGENIC FUNGI

FUNGI	DISEASE	FUNGICIDAL DILUTION	Test Method / Laboratory Reference
<i>Aspergillus brasiliensis</i> (Formerly <i>niger</i>)	Aspergillosis in poultry; turkeys are more susceptible than chickens	1:50 (Clean conditions)	2c
<i>Candida albicans</i>	Candidiasis	1:100	2a
<i>Fusarium oxysporum</i> f.sp. <i>cubense</i>	Fusarium wilt of bananas (Panama disease)	1:100	2b

GPC 8 MICROBIOLOGICAL PROFILE

THE EFFECT OF CONTACT TIME AND TEMPERATURE ON BACTERICIDAL ACTIVITY

EN 1656 was carried out with 5 and 30 minutes contact times, at the standard 10°C temperature and at 20°C and 30°C to determine the effect on the bactericidal dilution with a range of bacteria.

BACTERIA	TEST TEMPERATURE				Test Method / Laboratory Reference
	Time	10°C	20°C	30°C	
<i>Enterococcus hirae</i>	5 min	1:1000	1:1000	1:1000	1a), b), c)
	30 min	1:1000	1:1000	1:2000	
<i>Escherichia coli</i>	5 min	1:50	1:200	1:400	
	30 min	1:200	1:400	1:400	
<i>Proteus vulgaris</i>	5min	Fail 1:250	1:250	1:500	
	30min	1:250	1:1000	1:1000	
<i>Pseudomonas aeruginosa</i>	5 min	Fail 1:10	1:100	1:100	
	30 min	1:50	1:100	1:200	
<i>Salmonella enterica</i>	5 min	1:50	1:400	1:400	
	30 min	1:200	1:400	1:800	
<i>Staphylococcus aureus</i>	5 min	1:500	1:1000	1:1000	
	30 min	1:500	1:1000	1:1000	

The results indicate that the bactericidal activity of GPC8 is enhanced by increasing the temperature. This improved activity is greater against some bacteria than against others. In particular activity is enhanced against *Pseudomonas aeruginosa* the most resistant bacteria to many disinfectants including GPC8.

The results also indicate that to obtain the same level of activity with a shorter contact time a higher concentration of GPC8 is required in particular at 10°C and against the Gram negative bacteria *Escherichia coli*, *Proteus vulgaris*, *Pseudomonas aeruginosa* and *Salmonella enterica*.

GPC 8 MICROBIOLOGICAL PROFILE

APPENDIX I

TEST METHODS/TEST LABORATORY REFERENCES

EN 1656 and EN 1657 tests have been performed by the UKAS accredited Microbiology Laboratory (Testing Number 1108) of Evans Vanodine International Plc.

1. EN 1656

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area. This European Standard is applicable to products for use in the veterinary area, i.e. in the breeding, husbandry, production, transport and disposal of all animals except when in the food chain following death and entry to the processing industry.

- | | |
|---------------------|---|
| a) Test parameters: | 30 minute contact time, 10°C, hard water, high level soiling. |
| Requirements: | ≥5 log reduction ≡ 99.999% reduction. |
| b) Test parameters: | 5 and 30 minute contact time, 20°C, hard water, high level soiling. |
| Requirements: | ≥5 log reduction ≡ 99.999% reduction. |
| c) Test parameters: | 5 and 30 minute contact time, 30°C, hard water, high level soiling. |
| Requirements: | ≥5 log reduction ≡ 99.999% reduction. |

2. EN 1657

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in veterinary area

This European Standard is applicable to products for use in the veterinary area, i.e. in the breeding, husbandry, production, transport and disposal of all animals except when in the food chain following death and entry to the processing industry.

- | | |
|---------------------|---|
| a) Test parameters: | 30 minute contact time, 10°C, hard water, high level soiling. |
| b) Test parameters: | 30 minute contact time, 20°C, hard water, high level soiling. |
| c) Test parameters: | 2 hours contact time, 25°C, hard water, low level soiling. |
| Requirements: | ≥4 log reduction ≡ 99.99% reduction. |

3. Activity against *Leptospira interrogans*

Leptospira Reference Unit, Hereford

- | | |
|------------------|---|
| Test parameters: | 2 minutes contact time, room temperature, deionised water |
| Requirements: | No detection of Leptospires |

4. Activity against *Mycoplasma hyopneumoniae*

Mycoplasma Experience Ltd Surrey
Minimum inhibitory concentration test.

- | | |
|------------------|---------------------------------------|
| Test parameters: | Distilled water |
| Requirements: | Minimum concentration allowing growth |

GPC 8 MICROBIOLOGICAL PROFILE

APPENDIX I (continued)

5. Central Veterinary Laboratory

Test protocol specific to each virus.

Test parameters: 30 minute contact time, 4°C, hard water, organic soiling.
Requirements: ≥4 log reduction ≡ 99.99% reduction.

6. Chulalonghorn University, Bangkok, Thailand

Test protocol specific to each virus

Test parameters: 30 minute contact time, room temperature.
Requirements: ≥4 log reduction ≡ 99.99% reduction.

7. Liverpool University, Department of Veterinary Pathology

Test protocol specific to the virus

Test parameters: 30 minute contact time, room temperature.

8. Micropathology Ltd, Coventry

Test protocol specific to each virus

Test parameters: 10 minute contact time, room temperature.
Requirements: a) Hepatitis B: Destruction of surface antigen HBsAg
b) Hepatitis C: Reduction to an undetectable level
c) HIV: Reduction to an undetectable level

9. Poultry Research Laboratory, National Chun-Hsing University, Taichung, Taiwan,

Virus and organic material mixture is mixed with disinfectant, held for 30 minutes and diluted and titrated in embryonated eggs. Eggs alive after 7 days are tested for viral hemagglutinin. Comparison is made with a water control.

Test parameters: 30 minute contact time, 4°C, hard water, organic soiling.
Requirements: ≥4 log reduction ≡ 99.99% reduction.

10. Department of Veterinary Tropical Diseases, University of Pretoria, South Africa

Virus and disinfectant mixed, held for 30 minutes, diluted and titrated in embryonated eggs. Embryo mortalities are recorded every day for 5 days. Comparison is made with a Phosphate buffered saline control.

Test parameters: 30 minute contact time, room temperature, deionised water.
Requirements: ≥4 log reduction ≡ 99.99% reduction.

GPC 8 MICROBIOLOGICAL PROFILE

APPENDIX I (continued)

11. Onderstepoort Veterinary Institute, South Africa

Test protocol specific to each virus

Test parameters: 30 minute contact time, 20°C, hard water, organic soiling.

Requirements: ≥4 log reduction ≡ 99.99% reduction.

12. ATS Labs, Minnesota, USA

Virus is dried on a glass surface and exposed to the disinfectant for 30 minutes. After the contact time, the surviving virus is recovered and compared with a control.

a) Test parameters: 10 minutes contact time, 20°C, hard water.

b) Test parameters: 30 minutes contact time, 10°C, organic load.

Requirements: ≥4 log reduction ≡ 99.99% reduction.

13. Microbiotest, Sterling, Virginia, USA.

A portion of virus mixed with organic soil is dried on a sterile surface. A portion of disinfectant is applied to the surface and allowed to stand for 30 minutes at 10°C. After the contact period residual infectious virus is recovered and compared with a cell culture media control

Test parameters: 30 minutes contact time, 10°C, hard water, organic soiling.

Requirements: ≥3 log reduction when cytotoxicity is evident.

14. EN 14675 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area.

This European Standard is applicable to products for use in the veterinary area, i.e. in the breeding, husbandry, production, transport and disposal of all animals except when in the food chain following death and entry to the processing industry.

Test parameters: 30 minute contact time, 10°C, hard water, low and high level soiling.

Requirements: ≥4 log reduction ≡ 99.99% reduction.

15. The Pig Journal (2007) 60, 15-25, Efficacy of some disinfectant compounds against porcine bacterial pathogens, J R Thompson, N A Bell, M Rafferty.