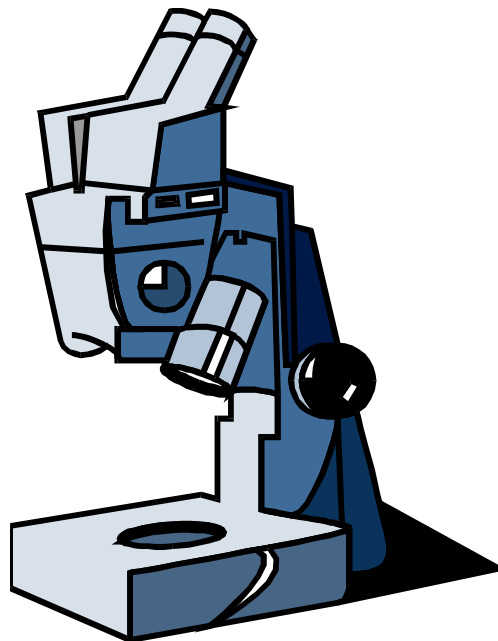


GPC8

MICROBIOLOGICAL PROFILE



GPC8 MICROBIOLOGICAL PROFILE

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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.

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

1. NATIONAL APPROVALS

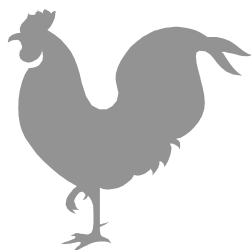
GPC8 is approved for use in the United Kingdom as a disinfectant against notifiable diseases.

GPC8 is approved under the Diseases of Animals (Approved Disinfectants) Orders by the Secretary of State for Environment, Food and Rural Affairs in England, Scotland and Wales.

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.

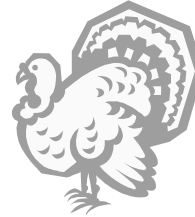
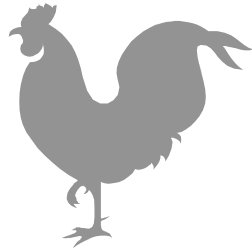
The approved dilution rates in the United Kingdom and Ireland are given below.

ORDER	APPROVED DILUTION RATES
Foot and Mouth	1:80
Swine Vesicular Disease	1:250
Diseases of Poultry Order and the Avian Influenza and Influenza of Avian Origin in Mammals	1:190
General	1:35



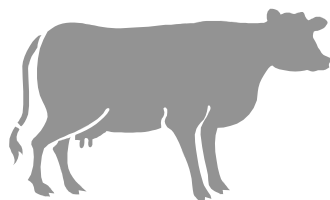
2 EFFECTIVENESS OF GPC8 AGAINST AVIAN PATHOGENIC BACTERIA AND FUNGI

BACTERIA	DISEASE	BACTERICIDAL DILUTION	Test Method / Laboratory Reference
<i>Enterococcus faecalis</i>	Enterococcal infection	1:800	1
<i>Escherichia coli</i>	Colisepticaemia in chickens, particularly broilers	1:200	1
<i>Pasteurella multocida</i>	Fowl cholera and pasteurellosis	1:400	1
<i>Proteus vulgaris</i>	Yolk sac infection in poultry	1:250	1
<i>Salmonella arizonae</i>	Salmonellosis	1:200	1
<i>Salmonella gallinarum</i>	Fowl typhoid	1:100	1
<i>Salmonella pullorum</i>	Pullorum disease (bacillary white diarrhoea)	1:200	1
<i>Salmonella typhimurium</i>	Salmonellosis	1:400	1
<i>Staphylococcus aureus</i>	Arthritis, bumblefoot and septicaemia	1:1000	1
FUNGI	DISEASE	FUNGICIDAL DILUTION	Test Method / Laboratory Reference
<i>Aspergillus niger</i>	Aspergillosis in poultry; turkeys are more susceptible than chickens	1:10 (Clean conditions)	2
<i>Candida albicans</i>	Candidiasis	1:100	2



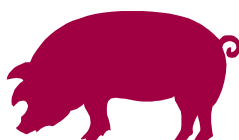
2 EFFECTIVENESS OF GPC8 AGAINST AVIAN PATHOGENIC VIRUSES

VIRUS	DISEASE	VIRUCIDAL DILUTION	Test Method / Laboratory Reference
Avian adenovirus	Egg Drop Syndrome	1:100	11
Avian influenza virus	Avian Influenza	1:200	10
Avian influenza virus Taiwan strain H6N1	Avian Influenza	1:220	13
Avian influenza virus H5N3	Avian Influenza	1:220	13
Avian influenza reassortant virus H3N2	Avian Influenza	1:200	14
Infectious Bronchitis virus	Infectious Bronchitis	1:100	8
Infectious Bursal Disease virus	Infectious Bursal Disease (Gumboro)	1:100	5
Infectious Laryngotracheitis virus	Infectious Laryngotracheitis	1:400	11
Marek's disease virus	Marek's Disease	1:200	15
Newcastle Disease virus	Newcastle Disease (Notifiable Disease)	1:190	7



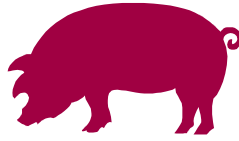
3 EFFECTIVENESS OF GPC8 AGAINST BOVINE PATHOGENIC BACTERIA FUNGI AND VIRUSES

BACTERIA	DISEASE	BACTERICIDAL DILUTION	Test Method / Laboratory Reference
<i>Escherichia coli</i>	Mastitis in dairy cattle and colibacillosis in calves	1:200	1
<i>Campylobacter jejuni</i>	Enteritis in man	1:1000	1
<i>Corynebacterium pseudotuberculosis</i>	Skin lesions	1:100	1
<i>Klebsiella pneumoniae</i>	Mastitis in dairy cattle	1:200	1
<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	1
<i>Staphylococcus aureus</i>	Mastitis in dairy cattle	1:1000	1
FUNGI	DISEASE	FUNGICIDAL DILUTION	Test Method / Laboratory Reference
<i>Aspergillus niger</i>	Aspergillosis and abortion in cattle	1:10 (Clean conditions)	2
<i>Candida albicans</i>	Candidiasis	1:100	2
VIRUS	DISEASE	VIRUCIDAL DILUTION	Test Method / Laboratory Reference
Foot and Mouth Disease Virus	Foot and Mouth (Notifiable Disease)	1:80	7



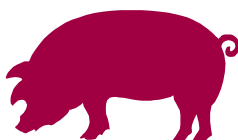
4 EFFECTIVENESS OF GPC8 AGAINST PORCINE PATHOGENIC BACTERIA

BACTERIA	DISEASE	BACTERICIDAL DILUTION	Test Method / Laboratory Reference
<i>Actinobacillus pleuropneumoniae</i> (App) Field isolate	Pleuropneumoniae, respiratory disease	1:100	17
<i>Bordetella bronchiseptica</i>	Atrophic rhinitis	1:100	1
<i>Bordetella bronchiseptica</i> Field isolate	Atrophic rhinitis	1:100	17
<i>Brachyspira hyodysenteriae</i> Field isolate	Swine dysentery	1:200	17
<i>Enterococcus faecalis</i>	Watery diarrhoea in piglets	1:800	1
<i>Enterococcus hirae</i>	Watery diarrhoea in piglets	1:1000	1
<i>Escherichia coli</i>	Bowel odema, colibacillosis	1:200	1
<i>Haemophila parasius</i> (Hps) Field isolate	Glässers disease	1:100	17
<i>Mycoplasma hyopneumoniae</i>	Enzootic pneumonia	1:64000 Bacteriostatic dilution	4
<i>Pasteurella multocida</i>	Pasteurellosis.	1:400	1
<i>Pseudomonas aeruginosa</i>	Cystitis and pyelonephritis	1:50	1
<i>Salmonella enteritidis</i>	Salmonellosis	1:200	1
<i>Staphylococcus aureus</i>	Mastitis	1:1000	1



4 EFFECTIVENESS OF GPC8 AGAINST PORCINE PATHOGENIC BACTERIA AND FUNGI

BACTERIA	DISEASE	BACTERICIDAL DILUTION	Test Method / Laboratory Reference
<i>Streptococcus suis</i>	Pneumonia	1:1000	1
<i>Streptococcus suis</i> Field isolate	Meningitis	1:400	17
FUNGI	DISEASE	FUNGICIDAL DILUTION	Test Method / Laboratory Reference
<i>Aspergillus niger</i>	Aspergillosis	1:10 (Clean conditions)	2
<i>Candida albicans</i>	Candidiasis	1:100	2

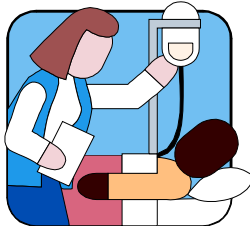


4 EFFECTIVENESS OF GPC8 AGAINST PORCINE PATHOGENIC VIRUSES

VIRUS	DISEASE	VIRUCIDAL DILUTION	Test Method / Laboratory Reference
African Swine Fever	African Swine Fever	1:50	12
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*	15
Foot and Mouth Disease virus	Foot and Mouth (Notifiable disease)	1:80	7
Parvo virus	Parvo disease	1:200	6
Porcine Influenza A (H1N1)	Influenza	1:400	16
Porcine Rotavirus	Epidemic Diarrhoea	1:200**	11
PRRS Virus	Porcine Reproductive and Respiratory Syndrome (Blue Ear Disease)	1:200	6
Swine Vesicular Disease virus	Swine Vesicular (Notifiable disease)	1:250	7
TGE Virus	Transmissible gastro-enteritis	1:200	7

* GPC8 passed the virucidal effectiveness test according to the US EPA regulatory agencies as a greater than $3\log_{10}$ reduction was demonstrated.

** $3\log_{10}$ reduction. In general the accepted criteria of virucidal efficacy is a $4\log_{10}$ reduction. Reductions of 2 to $3\log_{10}$ 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 $4\log_{10}$ reduction if the virus had produced cytopathic effects at a dilution of 10^{-6} .



5 EFFECTIVENESS OF GPC8 AGAINST HUMAN PATHOGENIC BACTERIA

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	1
<i>Campylobacter jejuni</i>	Enterocolitis, a major cause of diarrhoea	1:1000	1
<i>Pseudomonas aeruginosa</i>	Nosocomial infections (hospital acquired) wound infections	1:50	1
<i>Salmonella enteritidis</i>	Food poisoning (linked with poultry) resulting in gastro-enteritis	1:200	1
<i>Salmonella typhimurium</i>	Food poisoning (linked with cattle) resulting in gastro-enteritis	1:400	1
<i>Shigella sonnei</i>	Dysentery	1:200	1
<i>Staphylococcus aureus</i>	Boils, wound infections	1:1000	1
<i>Streptococcus pyogenes</i>	Throat infections	1:800	1



5 EFFECTIVENESS OF GPC8 AGAINST HUMAN PATHOGENIC FUNGI AND VIRUSES

FUNGI	DISEASE	FUNGICIDAL DILUTION	Test Method / Laboratory Reference
<i>Aspergillus niger</i>	Aspergillosis	1:10 (Clean conditions)	2
<i>Candida albicans</i>	Thrush	1:100	2
VIRUS	DISEASE	VIRUCIDAL DILUTION	Test Method / Laboratory Reference
Hepatitis B (HBV)	Hepatitis B	1:30	9
Hepatitis C (HCV)	Hepatitis C	1:30	9
Human Immunodeficiency type 1 (HIV)	AIDS	1:60	9

APPENDIX I

TEST METHODS/TEST LABORATORY REFERENCES

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

1. EN 1656:2000 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary field.

This European Standard is applicable to products for use in the veterinary field, 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, organic soiling.
Bactericidal criteria: 5 log reduction

2. EN 1657:2000

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

This European Standard is applicable to products for use in the veterinary field, 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, organic soiling.
Fungicidal criteria: 4 log reduction

3. Activity against *Leptospira interrogans*

Leptospira Reference Unit, Hereford

Test parameters: 2 minutes contact time, room temperature, deionised water
Bactericidal criteria: No detection of Leptospires

4. Activity against *Mycoplasma hyopneumoniae*

Mycoplasma Experience Ltd Surrey

Minimum inhibitory concentration test.

Test parameters: Distilled water
Bacteriostatic criteria: Minimum concentration allowing growth

APPENDIX I

TEST METHODS/TEST LABORATORY REFERENCES

5. Central Veterinary Laboratory

Test protocol specific to each virus.

Test parameters: 30 minute contact time, 4°C, hard water, organic soiling.

Virucidal criteria 4 log reduction

6. Chulalonghorn University, Bangkok, Thailand

Test protocol specific to each virus

Test parameters: 30 minute contact time, room temperature.

7. DEFRA Pirbright Laboratory

Test protocol specific to each virus

Test parameters: 30 minute contact time, 4°C, hard water, organic soiling.

8. Liverpool University, Department of Veterinary Pathology

Test protocol specific to the virus

Test parameters: 30 minute contact time, room temperature.

9. Micropathology Ltd, Coventry

Test protocol specific to each virus

Test parameters: 10 minute contact time, room temperature.

10. 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.

11. 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.

APPENDIX I

TEST METHODS/TEST LABORATORY REFERENCES

12. Agricultural Research Council Onderstepoort Veterinary Institute, Exotic diseases Division, South Africa

Virus and disinfectant mixed, held for 5 minutes, diluted and inoculated in duplicate 96 well plates. Wells examined daily for six days for haemadsorption. Comparison is made with a Phosphate buffered saline control.

Test parameters: 5 minute contact time, 5°C, distilled water.

13. National Chung-Hsing University, Taichung, Taiwan

Virus and organic soil mixture is added to disinfectant and held at 4°C for 30 minutes. After the contact period dilutions are prepared and used to inoculate embryonated eggs. Eggs are examined for viral haemagglutinin and titres compared with a water control.

Test parameters: 30 minutes, 4°C, hard water, organic soiling.

14. 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.

Test parameters: 30 minutes, 4°C, hard water, organic soiling.

15. 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.

APPENDIX I

TEST METHODS/TEST LABORATORY REFERENCES

16. EN 14675:2006 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary field.

This European Standard is applicable to products for use in the veterinary field, 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, organic soiling.
Virucidal criteria: 4 log reduction

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

APPENDIX II

GLOSSARY OF MICROBIOLOGICAL AND CHEMICAL TERMS

Agar	A derivative of marine sea-weed, used as a solidifying agent in <i>media</i> .
Acid	A substance with a pH less than 7.
Aerobic	Grows in oxygen atmosphere.
Alkali	Substance with a pH greater than 7.
Algicide	A chemical agent which, under defined conditions, is capable of killing algae including their <i>spores</i> .
Amphoteric	A class of surfactant, having both <i>anionic</i> and <i>cationic</i> properties.
Anaerobic	Grows in oxygen free atmosphere.
Anionic	A surfactant in which the surface active agent has a negative charge.
Antimicrobial	A substance capable of killing <i>micro-organisms</i> .
Antisepsis	The destruction or inhibition of <i>micro-organisms</i> on living tissues having the effect of limiting or preventing the harmful results of infection. It is not a synonym for <i>disinfection</i> .
Antiseptic	A chemical agent used in <i>antisepsis</i> .
Bacillus	A rod shaped bacteria.
Bactericide	A chemical agent which, under defined conditions, is capable of killing bacteria but not necessarily bacterial <i>spores</i> .
Bacteriostasis	A state of bacterial population in which, multiplication is inhibited.
Bacteriostat	A chemical agent which under defined conditions induces <i>bacteriostasis</i>
Biocide	A generalised term for a chemical agent capable of killing or inactivating <i>micro-organisms</i> . It embraces the more specific terms <i>algicide</i> , <i>bactericide</i> , <i>fungicide</i> , <i>sporicide</i> and <i>virucide</i> (see also <i>germicide</i>). Note. Pesticides are not considered to be <i>biocides</i> .
Black fluids	Coal-tar fractions solubilised with soaps.
Cationic	A surfactant in which the surface active agent has a positive charge
Chemical Sterilizing Agent	A chemical agent which, under defined conditions, leads to <i>sterilization</i> .
Chlorhexidine	A bisphenol compound used as <i>antiseptic</i> and <i>disinfectant</i> .

APPENDIX II

GLOSSARY OF MICROBIOLOGICAL AND CHEMICAL TERMS

Chlorine	A member of the Halogen group of elements. Frequently, but usually, incorrectly used to define the active species in, e.g. solutions of sodium hypochlorite.
Coccus	A spherical bacterium.
Disease	Any change from a general state of good health.
Disinfectant	A chemical agent which under defined conditions is capable of <i>disinfection</i> .
Disinfection	The destruction of <i>micro-organisms</i> , but not usually bacterial <i>spores</i> : it does not necessarily kill all <i>micro-organisms</i> , but reduces them to a level acceptable for a defined purpose, for example, a level which is harmful neither to health nor to the quality of perishable goods.
DNA	Deoxyribonucleic acid.
Formaldehyde	A colourless gas with a characteristic pungent odour. Used as a disinfectant in <i>fumigation</i> .
Fumigation	Exposure of enclosed spaces to action of gaseous or vapour-phase disinfectants or sterilants.
Fungus	A group of diverse unicellular and multicellular microorganisms (pl. fungi)
Fungicide	A chemical agent which under defined conditions is capable of killing fungi including their <i>spores</i> .
Fungistasis	A state of fungal population the development of which is inhibited.
Fungistat	A chemical agent which under defined conditions induces <i>Fungistasis</i> .
Genus	See <i>Species</i> .
Germ	A vague term which should be avoided. A <i>micro-organism</i> which can be harmful.
Germicide	A vague term which should be avoided. An agent under defined conditions, which is capable of killing <i>germs</i> .
Glutaraldehyde	A broad spectrum biocide used as an active ingredient in formulated disinfectants.
Gram Stain	Stain technique used to classify bacteria into two groups: Gram negative or Gram positive.
Halogens	A group of chemicals consisting of e.g. Fluorine, <i>Chlorine</i> , <i>Iodine</i> and Bromine.

APPENDIX II

GLOSSARY OF MICROBIOLOGICAL AND CHEMICAL TERMS

Hydrogen Peroxide	A bleaching/oxidising agent used as a disinfectant.
Hypochlorite	Usually sodium hypochlorite, solutions of hypochlorite are oxidising disinfectants producing the biocidally active hypochlorite anion and hypochlorous acid.
Iodine	A <i>Halogen</i> similar to <i>chlorine</i> but more stable and less reactive.
Iodophor	<i>Iodine</i> in solution of surfactant with stabiliser.
Media	A nutrient rich solid or liquid (agar or broth) used to grow <i>micro-organisms</i> .
Microbe	An alternative expression for <i>micro-organism</i> .
Micro-organism	A microscopic entity capable of replication. It includes bacteria, viruses and the microscopic forms of algae, fungi and <i>protozoa</i> .
Motile	Describes organisms which can move independently.
Mould	Any fungus that forms visible <i>mycelia</i> growth.
Mycelium	A visible mass of tangled filaments of fungal growth.
Nucleic Acids	An organic compound composed of nucleotides <i>DNA</i> and <i>RNA</i>
Oocyst	An oval body in the reproduction cycle of certain <i>protozoa</i> .
Pathogen	An organism that causes <i>disease</i> animals, plants or <i>micro-organisms</i> .
Peracetic acid	Acid produced by combination of acetic acid and <i>hydrogen peroxide</i> .
Phenol	Chemical derived from coal tar. Used as a <i>disinfectant</i> .
Preservation	Maintaining numbers of <i>micro-organisms</i> at low levels i.e. low enough to make food safe to eat or to prevent spoilage.
Protozoa	Unicellular <i>micro-organisms</i> . Classified in the Animal Kingdom.
Quaternary Ammonium	
Compound	A <i>cationic surfactant</i> with strong bactericidal but weak detergent properties.
RNA	Ribonucleic acid involved in protein synthesis.
Sanitization	A term used mainly in the food and catering industry. A process of both cleaning/disinfecting utensils, equipment and surfaces.
Sanitizer	A chemical agent used for <i>sanitization</i> .
Somatic	Refers to the “body” or main part of a cell. Does not include reproductive structures such as <i>spores</i> .

APPENDIX II

GLOSSARY OF MICROBIOLOGICAL AND CHEMICAL TERMS

Species	Fundamental rank of the classification system. (Two or more species grouped together are classed as a <i>genus</i>).
Spirochete	A twisted bacterial rod with a flexible cell wall containing axial filaments for <i>motility</i> .
Spore	A highly resistant structure formed from <i>somatic</i> cells in several genera of bacteria. e.g. <i>Bacillus</i> . Also a reproductive structure formed by fungi.
Sporicide	A chemical agent which, under defined conditions, is capable of killing bacterial <i>spores</i> .
Sterile	Free from all living <i>micro-organisms</i> .
Sterilization	A process which renders an item <i>sterile</i> .
Sterilizing agent	An agent or combination of agents which under defined conditions leads to <i>sterilization</i> .
Surfactant	A surface active agent.
Toxin	A poisonous substance produced by a <i>species</i> of <i>micro-organism</i> .
Vibrio	A form of <i>bacteria</i> occurring as a curved rod.
Virucide	A chemical agent which, under defined conditions, is capable of killing or inactivating <i>viruses</i>
Virus	A non-cellular entity consisting of protein and <i>nucleic acid</i> . Can only replicate after entry into specific types of living cell.
White fluids	Prepared by emulsifying tar fractions.
Zoonosis	Any <i>disease</i> which can be transmitted from animal to man and vice-versa