



Biogen Microbiological Profile



90 Holme Lane
Hillsborough
Sheffield
S6 4JW

Tel: 0114 2346730
Fax: 0114 2346751

info@skychemicals.co.uk
www.skychemicals.co.uk

BIOGEN MICROBIOLOGICAL PROFILE

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INTRODUCTION

BIOGEN is an unperfumed, multi-purpose cleaner and terminal disinfectant. It is recommended for use in nursing homes and healthcare establishments.

BIOGEN helps prevent the spread of infection; it kills a range of pathogenic micro-organisms including the viruses that cause Hepatitis B, Human Immunodeficiency Disease and the Norovirus surrogate Feline Calicivirus; the bacteria MRSA (Methicillin Resistant *Staphylococcus aureus*) and the bacteria and spores of *Clostridium difficile*.

BIOGEN has been tested using European Standard methods. These methods have superseded certain British Standards e.g. BS 541 Rideal Walker (RW), BS 6905 Kelsey-Sykes, Minimum Inhibitory Concentrations (MIC), BS 6471 Efficacy of Quaternary Ammonium Compounds (QAC).

The tests were carried out in the UKAS accredited Microbiology Laboratory of Evans Vanodine International PLC, Blu Scientific at Glasgow Caledonian University and at the relevant expert virology laboratory.

Results are presented in the following tables with effective dilution rates expressed as parts of product in parts of water.

European Standard bactericidal methods specify four reference bacteria to be tested, with additional bacteria if required. Additional organisms were tested using EN 1276 and were less resistant than the reference organisms.

BIOGEN was also tested using EN 1276 with short contact times.

THE RECOMMENDED USE DILUTIONS HAVE BEEN DETERMINED FROM THE TEST RESULTS AND ARE BASED ON ACTIVITY AGAINST THE MOST RESISTANT REFERENCE BACTERIA/VIRUS

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

BIOGEN MICROBIOLOGICAL PROFILE

1 BACTERICIDAL ACTIVITY UNDER CLEAN CONDITIONS

TEST METHOD BSEN 1276 TEST TEMPERATURE 20°C, CONTACT TIME 5 MINUTES			
BACTERIA	DISEASE	BACTERICIDAL DILUTION	TEST REFERENCE
<i>Enterococcus hirae</i>	Urinary tract infections	1:400	1
<i>Escherichia coli</i> "0157"	Food poisoning, which can result in enteritis and haemolytic uraemic syndrome (characterised by renal failure)	1:50	1
<i>Pseudomonas aeruginosa</i>	Opportunistic pathogen, wound, burn infections	1:20	1
<i>Staphylococcus aureus</i>	Skin, bone and wound infections	1:400	1

1 BACTERICIDAL ACTIVITY UNDER DIRTY CONDITIONS

TEST METHOD: BSEN 1276 TEST TEMPERATURE 20°C, CONTACT TIME 5 MINUTES			
BACTERIA	DISEASE	BACTERICIDAL DILUTION	TEST REFERENCE
<i>Enterococcus hirae</i>	Urinary tract infections	1:200	1
<i>Escherichia coli</i> "0157"	Food poisoning, which can result in enteritis and haemolytic uraemic syndrome (characterised by renal failure)	1:25	1
<i>Escherichia coli</i> Extended Spectrum Beta Lactamase	Urinary tract infections. Resistant to certain antibiotics i.e. cephalosporins	1:10	1
<i>Campylobacter jejuni</i>	Enterocolitis. A major cause of diarrhoea	1:200	1
<i>Clostridium difficile</i>	Common cause of antibiotic-associated diarrhoea (AAD)	1:10	1
Methicillin Resistant <i>Staphylococcus aureus</i>	Skin, bone and wound infections, pneumonia. Resistant to treatment with the antibiotic Methicillin	1:100	1
<i>Proteus vulgaris</i>	Urinary tract infections	1:200	1
<i>Pseudomonas aeruginosa</i>	Opportunistic pathogen, wound, burn infections	1:10	1
<i>Salmonella enteritidis</i>	Food poisoning (linked with poultry) resulting in gastro-enteritis	1:40	1
<i>Salmonella typhimurium</i>	Food poisoning (linked with cattle) resulting in gastro-enteritis	1:20	1
<i>Shigella sonnei</i>	Dysentery	1:25	1
<i>Staphylococcus aureus</i>	Skin, bone and wound infections	1:200	1
<i>Streptococcus pyogenes</i>	Throat infections	1:200	1

1 BACTERICIDAL ACTIVITY UNDER DIRTY CONDITIONS USING SHORTER CONTACT TIMES

TEST METHOD: BSEN 1276 TEST TEMPERATURE 20°C, CONTACT TIME 30 SECONDS			
BACTERIA	DISEASE	BACTERICIDAL DILUTION	TEST REFERENCE
<i>Enterococcus hirae</i>	Urinary tract infections	1:50	1
<i>Escherichia coli</i>	Food poisoning, urinary tract infections	1:5	1
<i>Pseudomonas aeruginosa</i>	Opportunistic pathogen, wound, burn infections	1:10	1
<i>Staphylococcus aureus</i>	Skin, bone and wound infections	1:50	1

2 BACTERICIDAL ACTIVITY UNDER CLEAN CONDITIONS USING A SURFACE TEST METHOD

TEST METHOD EN 13697 TEST TEMPERATURE 20°C, CONTACT TIME 5 MINUTES			
BACTERIA	DISEASE	BACTERICIDAL DILUTION	TEST REFERENCE
<i>Enterococcus hirae</i>	Urinary tract infections	1:80	2
<i>Escherichia coli</i>	Food poisoning, urinary tract infections	1:100	2
<i>Pseudomonas aeruginosa</i>	Opportunistic pathogen, wound, burn infections	1:10	2
<i>Staphylococcus aureus</i>	Skin, bone and wound infections	1:100	2

2 BACTERICIDAL ACTIVITY UNDER DIRTY CONDITIONS USING A SURFACE TEST METHOD

TEST METHOD EN 13697 TEST TEMPERATURE 20°C, CONTACT TIME 5 MINUTES			
BACTERIA	DISEASE	BACTERICIDAL DILUTION	TEST REFERENCE
<i>Enterococcus hirae</i>	Urinary tract infections	1:50	2
<i>Escherichia coli</i>	Food poisoning, urinary tract infections	1:100	2
<i>Pseudomonas aeruginosa</i>	Opportunistic pathogen, wound, burn infections	1:10	2
<i>Staphylococcus aureus</i>	Skin, bone and wound infections	1:50	2

3 SPORICIDAL ACTIVITY UNDER CLEAN CONDITIONS

TEST METHOD EN 13704 TEST TEMPERATURE 20°C, CONTACT TIME 60 MINUTES			
BACTERIA	DISEASE	BACTERICIDAL DILUTION	TEST REFERENCE
<i>Clostridium difficile</i>	Common cause of antibiotic-associated diarrhoea (AAD)	1:5	3

4 FUNGICIDAL ACTIVITY UNDER CLEAN CONDITIONS

TEST METHOD: BSEN 1650 TEST TEMPERATURE 20°C, CONTACT TIME 15 MINUTES			
FUNGI	DISEASE	FUNGICIDAL DILUTION	TEST REFERENCE
<i>Aspergillus niger</i>	Aspergillosis	1:10	4
<i>Candida albicans</i>	Thrush	1:200	4

4 FUNGICIDAL ACTIVITY UNDER DIRTY CONDITIONS

TEST METHOD: BSEN 1650 TEST TEMPERATURE 20°C, CONTACT TIME 15 MINUTES			
FUNGI	DISEASE	FUNGICIDAL DILUTION	TEST REFERENCE
<i>Aspergillus niger</i>	Aspergillosis	UNDILUTED	4
<i>Candida albicans</i>	Thrush	1:50	4

5 VIRUCIDAL ACTIVITY

ROOM TEMPERATURE, CONTACT TIME 10 MINUTES			
VIRUS	DISEASE	VIRUCIDAL DILUTION	TEST REFERENCE
Hepatitis B (HBV)	Hepatitis B	1:25	5
Human Immunodeficiency type 1 (HIV)	AIDS	1:5	6
ROOM TEMPERATURE, CONTACT TIME 5 MINUTES			
Feline Calicivirus (Noro virus surrogate)	Surrogate for gastroenteritis (winter vomiting disease)	1:25	7

APPENDIX I

TEST METHOD REFERENCES

Laboratory tests for bactericidal and fungicidal activity, have been performed by the UKAS accredited Microbiology Laboratory (Testing Number 1108) of Evans Vanodine International Plc. Except EN 1276 and EN 13704 against *Clostridium difficile*, performed by BluScientific at Glasgow Caledonian University.

1 EUROPEAN STANDARD: BSEN 1276:1997

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic, and institutional areas

Designed to test bactericidal products specifically for use in the Food and Catering Industry. It is carried out under “dirty” (representative of surfaces which are known to or may contain organic and/or inorganic materials) and “clean” (representative of surfaces which have received a satisfactory cleaning programme and/or are known to contain minimal levels of organic and/or inorganic materials) conditions. Additional temperatures and contact times were used as well as the obligatory test conditions.

2 EUROPEAN STANDARD: BSEN 13697:2001

Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Without mechanical action.

Designed to test bactericidal and fungicidal products on stainless steel surfaces inoculated with bacteria and an organic interfering substance. It is carried out under “dirty” (representative of surfaces which are known to or may contain organic and/or inorganic materials) and “clean” (representative of surfaces which have received a satisfactory cleaning programme and/or are known to contain minimal levels of organic and/or inorganic materials) conditions.

3 EUROPEAN STANDARD: EN 13704 : 2002

Chemical disinfectants – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.

Designed to test sporicidal products using the spore forming bacteria *Bacillus subtilis*, under conditions representative of surfaces which have received a satisfactory cleaning programme and/or are known to contain minimal levels of organic and/or inorganic materials. **BIOGEN** was tested against the spores of *Clostridium difficile* using the test method. This does not imply sporicidal activity against other bacterial spores.

APPENDIX I

TEST METHOD REFERENCES

FUNGICIDAL ACTIVITY

4 **EUROPEAN STANDARD: BSEN 1650 : 1998**

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

Designed to test fungicidal products specifically for use in the Food and Catering Industry. It is carried out under “dirty” (representative of surfaces which are known to or may contain organic and/or inorganic materials) and “clean” (representative of surfaces which have received a satisfactory cleaning programme and/or are known to contain minimal levels of organic and/or inorganic materials) conditions.

VIRUCIDAL ACTIVITY

All virus tests were carried out by expert virology laboratories.

5 **Hepatitis B (HBV)**

An indirect method of measuring the activity against Hepatitis B was used as this virus cannot be propagated in tissue culture. The test method relies on the destruction of the surface antigen of HBV. The method is recommended by the German Association for the Control of Viral Diseases and usually makes greater demands on the concentration or contact time of the disinfectant than methods such as the demonstration of destruction of HBV DNA polymerase. The test was carried out at room temperature with a 10 minute contact time. No surface antigen remained detectable at the end of the contact time.

6 **Human Immunodeficiency Virus Type 1 (HIV)**

The test method uses an assay for measuring the concentration of a virus specific molecule in an infected blood sample following exposure of the sample to the disinfectant. The loss of detectable virus specific molecules is used as a marker of virus ‘killing’. The assay is likely to underestimate the effectiveness of the disinfectant against HIV because the molecule detected is relatively resistant to chemical degradation, it is however, essential for infectivity and so its disappearance following treatment is a good indication of virus inactivation.

7 Feline Calicivirus

EN 14476:2005 Chemical disinfectants and antiseptics – Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine

The test was carried out on Feline Calicivirus as this is the accepted surrogate virus for Norovirus the cause of “winter vomiting disease”. Norovirus cannot be grown under laboratory conditions and therefore a surrogate is used to provide information on the likely activity of a product against Norovirus.

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.
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