

## GENEFECT

### LONZA FORMULATION<sup>®</sup> S-21

#### Disinfectant/Cleaner and Sanitizer

##### Description

**Lonza Formulation<sup>®</sup> S-21** is a broad spectrum, one-step, hard surface disinfectant/cleaner and sanitizer. When used as directed, this product will deliver effective biocidal action against bacteria, fungi, viruses and exceptional cleaning performance. This formulation is a blend of a premium active ingredient, Bardac<sup>®</sup> 208M, and inerts: surfactants, builders and chelates. Biocidal performance is attained when this product is properly diluted at 2 oz. per gallon of water or 1:64. **Lonza Formulation<sup>®</sup> S-21** can be used to disinfect a wide variety of hard surfaces such as floors, walls, and countertops in hospitals, households, and institutions. Other areas of use are in restaurants, athletic facilities, schools, restrooms, laboratories, and transportation vehicles and facilities. Other areas of use are in restaurants, athletic facilities, schools, restrooms, federally inspected Meat and Poultry plants, salons, laboratories, and transportation vehicles and facilities. Please see our EPA registered label for complete list of areas of use.

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##### Formula:

<u>Active Ingredient</u>	<u>Lonza Formulation<sup>®</sup> S-21 %wt/wt</u>
Bardac <sup>®</sup> 208M (80% active)	6.875
<u>Inert Ingredients</u>	
Tetrasodium ethylenediamine tetraacetate 38% (Na <sub>4</sub> EDTA)	5.0
Sodium metasilicate pentahydrate <sup>1</sup>	0.50
Nonionic surfactant <sup>1</sup>	2.50
Fragrance <sup>1</sup>	0.1 to 0.25
Dye <sup>1</sup>	0.001 to 0.10
Water	q.s. to 100.00

<sup>1</sup> See list of approved suppliers from Confidential Statement of Formulation.

##### Regulatory Summary

EPA Registration No: 6836-75  
Former USDA Authorization C1  
California Status Registered  
Canadian PCP No. 18451

##### Physical Properties

pH of Concentrate	12.4	Flash Point(PMCC)	>100°C
Specific Gravity@25°C	1.020	% Quat (mol.wt. 342)	5.5
Wt per Gallon@ 25°C	8.42	% Volatile	89.5-90.5
Canadian DIN No.	2008459		

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## Summary of Antimicrobial Test Results

**Lonza Formulation® S-21** is a "One-Step" Hospital Disinfectant, Virucide, Fungicide, Mildewstat, Sanitizer and Cleaner. Listed below, and in the following pages, is a summary of the Antimicrobial Claims and a review of the test results.

<b>Claim:</b> Disinfectant	<b>Contact Time:</b> 10 minutes	<b>Organic Soil:</b> 5%	<b>Water Conditions:</b> 400 ppm as CaCO <sub>3</sub>
<b>Test Method:</b> Official Method of the AOAC, 14 Edition Use-Dilution Method			

Organism	ATCC#	Dilution	Replicates	Results
Acinetobacter baumannii	19606	859 ppm (2 ox/gal)	10, 10	0/10, 0/10
Brevibacterium ammoniagenes	6871	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Campylobacter jejuni	29428	859 ppm	10, 10	0/10, 0/10
Citrus Canker	USDA 46190	2000 ppm (5 oz/gal)	10, 10	0/10, 0/10
Enterobacter aerogenes	13408	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Enterococcus faecalis	11700	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Enterococcus faecalis - Vancomycin res.	51299	859 ppm	10, 10	0/10, 0/10
Escherichia coli	11229	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Escherichia coli ESBL <sup>4</sup>	CU-209	848 ppm	10, 10	0/10, 0/10
Klebsiella pneumoniae	4352	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Legionella pneumophila	33153	848 ppm	10, 10	0/10, 0/10
Pseudomonas aeruginosa	15442	859 ppm	60, 60, 60, 40	0/60, 0/60, 0/60, 0/40
Pseudomonas cepacia	17765	859 ppm	10, 10	0/10, 0/10
Pseudomonas cepacia	25416	859 ppm	10, 10	0/10, 0/10
Pseudomonas cepacia	25608	859 ppm	10, 10	0/10, 0/10
Salmonella (choleraesuis) enterica	10708	859 ppm	60, 60, 60, 40	0/60, 0/60, 0/60, 0/40
Salmonella schottmuelleri	10719	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Salmonella typhi	6539	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Serratia marcescens	274	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Shigella dysenteriae	9380	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Staphylococcus aureus	6538	859 ppm	60, 60, 60, 40	0/60, 0/60, 0/60, 0/40
Staphylococcus aureus <sup>1</sup>	33592	859 ppm	10,10	0/10, 0/10
Staphylococcus aureus <sup>2</sup>	14154	859 ppm	10,10	0/10, 0/10
Staphylococcus aureus <sup>3</sup> (VISA)	CDC HIP-5836	859 ppm	10,10	0/10, 0/10
Staphylococcus aureus (MRSA) Community Associated	NRS 384 USA 300	848 ppm	10,10	0/10, 0/10
Staphylococcus aureus (MRSA) Community Associated	NRS 123 USA 400	848 ppm	10,10	0/10, 0/10
Streptococcus pyogenes	12344	859 ppm	10, 10, 10	0/10, 0/10, 0/10
Vibrio cholerae	14035	859 ppm	10,10	0/10, 0/10

<sup>1</sup> Methicillin Resistant strain - (MRSA)

<sup>2</sup> Multidrug Resistant: Tetracycline, penicillin, streptomycin, erythromycin; susceptible to chloramphenicol

<sup>3</sup>Reduced Susceptibility to Vancomycin

<sup>4</sup> Enzyme producing, antibiotic resistant

**Conclusion:** All lots of **Lonza Formulation® S-21** effectively killed the above listed bacteria as specified in the test performance standards. **Lonza Formulation® S-21** meets EPA requirements for hard surface disinfectant claims in hospital and medical environments when diluted 1:64 in 400 ppm synthetic hard water in the presence of 5% organic soil.

<b>Claim:</b> Virucide	<b>Contact Time:</b> Varies	<b>Organic Soil:</b> 5%	<b>Water Conditions:</b> 400 ppm as CaCO <sub>3</sub>
<b>Test Method:</b> EPA Guidelines			

Organism	Source of Virus or ATCC#	Host System; Cytopathic Effect	Contact Time	Dilution	Replicates	Results Log 10 Reduction
Adenovirus Type 5	ATCC VR-5	Human Epithelioma #2 cells; lytic cytopathic effect	10 Min.	3391 ppm (8 oz/gal)*	4	>4.0
Adenovirus Type 7	ATCC VR-7	H1-HeLa, ATCC CRL - 1958	10 Mins	3391 ppm (8 oz/gal)*	3,3	>4.0
Hepatitis B (HBV)	Hepadnavirus Testing	Hepatitis B (w/ 5 % serum)	10 Min	859 ppm (2 oz/gal)	4, 4	>4.2, >4.2
Hepatitis C (HCV)	Bovine Viral Diarrhea Virus	MDBK cells	10 Min.	848 ppm	2	>5.0
Herpes Simplex Type 1	HSV-1 Sabin	Human Epithelioma #2 cells; lytic cytopathic effect	10 Min.	859 ppm	8	>4.0
Herpes Simplex Type 2	HSV-II Sabin (CL-5)	Human Epithelioma #2 cells; lytic cytopathic effect	10 Min.	859 ppm	8	>3.5
HIV-1 (AIDS Virus)	HTLV-III <sub>B</sub> ; Electronucleonics Inc.	MT2 cells; lytic cytopathic effect	1 Min.	859 ppm	4	>4.5
Human Coronavirus	ATCC VR-740	MRC-5 Cells	10 Min.	849 ppm	2	>3
Influenza A/Brazil	A/Brazil 11/78 (H1N1) E-7 ; CDC	10-day chick embryo; death of embryo	10 Min.	859 ppm	4	>5.5
Norwalk (Feline Caliciviruses the surrogate for Norwalk virus)	Feline Caliciviruse (FSV) University of Ottawa	Crandell feline kidney (CrFK) cells	10 Min.	848 ppm	3,3,3,3	>6.59, >6.58
Respiratory Syncytial Virus	VR-26	Hep-2 (Human Larynx carcimoma)	10 min	859 ppm	2	>4.75
Rotavirus	Strain WA	MA 104 cells	10 Min	848 ppm	8	>5.5

SARS associated Coronavirus	SARS associated coronavirus strain 200300592	Vero E6 cells	10 Min.	848 ppm	4	≥3.67
Vaccinia	Wyeth strain	Human Epithelioma #2 cells fed with MEM95CS5; lytic cytopathic effect	10 Min.	859 ppm	8	>5.0

\*Note, the higher dilution is required for efficacy

**Conclusion:** All lots of **Lonza Formulation® S-21** effectively inactivated the above listed viruses as specified in the test performance standards. **Lonza Formulation® S-21** meets EPA requirements for hard surface virucidal claims in hospital and medical environments when diluted as indicated in 400 ppm synthetic hard water in the presence of 5% organic soil.

<b>Claim:</b> Fungicide	<b>Contact Time:</b> 10 minutes	<b>Organic Soil:</b> Pre-Cleaned Surface	<b>Water Conditions:</b> 400 ppm as CaCO <sub>3</sub>
<b>Test Method:</b> Official Method of Analysis of the AOAC, - Fungicidal Test.			

Organism	ATCC#	Dilution	Replicates	Results		
				5 Min	10 Min	15 Min
Trichophyton mentagrophytes	9533	859 ppm (2 oz/gal)	4	0/4 +	0	0

<b>Claim:</b> Fungicide	<b>Contact Time:</b> 10 minutes	<b>Organic Soil:</b> 5%	<b>Water Conditions:</b> 250 ppm as CaCO <sub>3</sub>
<b>Test Method:</b> Official Method of Analysis of the AOAC, Fungicidal Test – Use-dilution			

Organism	ATCC#	Dilution	Replicates	Results
Trichophyton mentagrophytes	9533	1696 ppm (4 oz/gal)	10, 10	0/10, 0/10

**Conclusion:** All lots of **Lonza Formulation® S-21** effectively killed Trichophyton mentagrophytes as specified in the test performance standards. **Lonza Formulation® S-21** is an effective fungicide for nonporous inanimate hard surfaces when diluted either at 1) 1:64 (849 ppm) in 400ppm synthetic hard water (precleaned surface) or 2) 1:64 (849 ppm) in 250 ppm synthetic hard water in the presence of 5% organic soil.

<b>Claim:</b> Mildewstat	<b>Contact Time:</b> 10 minutes	<b>Organic Soil:</b> 5%	<b>Water Conditions:</b> 400 ppm as CaCO <sub>3</sub>
<b>Test Method:</b> Mildewstat (Mold and Mildew Control) - EPA - 6-201 Mildewstat on Hard Surfaces			

Organism	ATCC#	Dilution	Replicates	Results
Aspergillus niger	6275	859 ppm (2 oz/gal)	10, 10, 10	0/10, 0/10, 0/10

**Conclusion:** All lots of **Lonza Formulation® S-21** were found to be effective against Aspergillus niger as specified in the test performance standards described above. **Lonza Formulation® S-21** is an effective mildewstat for nonporous inanimate hard surfaces when diluted 1:64 in 400 ppm synthetic hard water in the presence of 5% organic soil.

<b>Claim:</b> Sanitizer Non-Food	<b>Contact Time:</b> 60 seconds	<b>Organic Soil:</b> 5%	<b>Water Conditions:</b> 500 ppm CaCO <sub>3</sub>
<b>Test Method:</b> Sanitizer Non-Food Contact Surfaces- EPA Dis.5 - For Inanimate, Non- Food Contact Surfaces			

Organism	ATCC#	Dilution	Replicates	Results % Reduction
Klebsiella pneumoniae	4352	200 ppm(0.5 oz/gal)	6	>99.999
Staphylococcus aureus	6538	200 ppm	6	>99.999

**Conclusion:** All lots of **Lonza Formulation® S-21** effectively killed the above listed bacteria as specified in the test performance standards with greater than 99.999% reduction within one minute. **Lonza Formulation® S-21** is an effective Non-Food Contact Sanitizer against the above listed bacteria on nonporous inanimate hard surfaces when diluted to 200 ppm in 500 ppm synthetic hard water in the presence of 5% organic soil.

<b>Claim:</b> Virucide	<b>Contact Time:</b> Varies	<b>Organic Soil:</b> 5%	<b>Water Conditions:</b> 400 ppm as CaCO <sub>3</sub>
<b>Test Method:</b> EPA Guidelines			

Organism	Source of Virus or ATCC#	Host System; Cytopathic Effect	Contact Time	Dilution	Replicates	Results Log 10 Reduction
Avian Influenza (H5N1)	Strain H5N1-PR8/CDC-RG CDC#2006719965	Rhesus Monkey Kidney cells (RMK)	10 Min	848 ppm (2 oz/gal)	4,4,4	≥4.0
Canine Distemper Virus	Canine Distemper Strain Ondesterpoort	Vero CCL-81	10 Min	848 ppm	2	>4.0
Feline Calicivirus	Feline Calicivirus (FSV) Univ of Ottawa	Crandell Feline Kidney (Crk cells)	10 Min	848 ppm	3,3,3,3	>6.59, >6.58
Newcastle Disease Virus	NDV Atcc VR-108 Strain B-1 Hitchner and Blacksburg	Embryonated Chicken Eggs	10 Min.	848 ppm	4,4	>4.0
Pseudorabies Virus	PRV Strain Aujeszkies PT-1 Origin	MDBK Cells	10 Min.	848 ppm	2	>4.0

**Conclusion:** All lots of **Lonza Formulation® S-21** were found to be effective against the above animal viruses as specified in the EPA test performance standards. **Lonza Formulation® S-21** is an effective virucide for nonporous inanimate hard surfaces when diluted 1:64 in 400 ppm synthetic hard water in the presence of 5% organic soil.

## Summary of Antimicrobial Efficacy – Etiology<sup>5</sup>

Pathogenic Microorganism	Description
Acinetobacter baumannii	Gram negative (spherical shape) bacteria. Occurs in soil, water and sewage. A nosocomial infection can cause septicemia, meningitis and urinary tract infections.
Adenovirus Type 5	Lipophilic (enveloped) DNA virus, (one of several) causative agent for colds and other respiratory ailments
Adenovirus Type 7	Human adenoviruses are known to cause a variety of illnesses, including cystitis, diarrhea, intussusception, meningoencephalitis, epidemic keratoconjunctivitis, and encephalitis. Communitywide outbreaks of respiratory illness attributable to adenovirus, particularly serotypes 3, 4, 7, and 21, have also been described in civilian and military populations
Aspergillus niger	Black mold, found in shower and dressing rooms. Environmental contaminant may also cause aspergillosis.
Brevibacterium ammoniagenes	Gram positive bacteria environmental contaminant. Associated with industrial contamination.
Campylobacter jejuni	Gram negative bacteria associated with acute gastroenteritis. Spread by anal/oral route of infection, resulting in diarrhea outbreaks.
Canine Distemper Virus	Canine distemper is a contagious, incurable, often fatal, multisystemic viral disease that affects the respiratory, gastrointestinal, and central nervous systems. Distemper is caused by the canine distemper virus (CDV).
Enterobacter aerogenes	Gram negative bacteria spread by anal/oral route of infection. Associated with bacteremia, respiratory, wound and urinary tract infections.
Escherichia coli	Gram negative bacteria spread by anal/oral route of infection, resulting in diarrhea outbreaks. Associated with urinary tract infections and bacteremia.
Feline Calicivirus	Calicivirus affects the upper respiratory system, the eyes, the musculoskeletal system, and the gastrointestinal tract.
Herpes Simplex Type 1&2	Lipophilic (enveloped) DNA virus, may result in oral mucocutaneous lesions. Associated with most orofacial herpes and HSV encephalitis.
HBV (Hepatitis B Virus)	Lipophilic (enveloped) DNA virus of the Hepadnaviridae family. Causative agent of Hepatitis B (serum hepatitis).
HCV (Hepatitis C Virus)	Major cause of acute hepatitis and chronic liver disease, including cirrhosis and liver cancer. It is an enveloped RNA virus in the flaviviridae family
HIV-1 (AIDS Virus)	Lipophilic (enveloped) RNA retrovirus. Human Immunodeficiency Virus. Known to be the etiologic agent of Acquired Immunodeficiency Syndrome (AIDS).
Human Coronavirus	Monogeneric group of RNA containing viruses that are associated with respiratory infections.
Influenza A/Brazil	Lipophilic (enveloped) RNA virus. Causative agent in viral flu. Causes flu epidemics in nearly 2 of every 3 years.
Klebsiella pneumoniae	Gram negative bacteria associated with severe pneumonia, bacteremia and urinary tract infections.
Legionella pneumophila	A motile rod-shaped, gram-negative, aerobic facultative intracellular bacterium that causes legionellosis (respiratory infections).
Newcastle Disease Virus	NDV is a contagious and fatal viral disease affecting most species of birds. A death rate of almost 100 percent can occur in unvaccinated poultry flocks. NDV can infect and cause death even in vaccinated poultry.

Norwalk Virus	A genus of viruses of the family <i>Caliciviridae</i> . Recent scientific findings reveal that the genus causes around 50% of all gastroenteritis (stomach pain, diarrhea, and vomiting) around the world
<i>Pseudomonas aeruginosa</i>	Gram negative bacteria identified as a major cause of hospital acquired (nosocomial) infections. Causes wound infections (especially burn), meningitis, pneumonia and eye infections. Required for Hospital Disinfectants.
<i>Pseudomonas cepacia</i>	Gram negative bacteria identified as a cause of hospital acquired (nosocomial) infections. Causes septicemia, meningitis, endocarditis, pneumonia, eye wound and urinary tract infections, especially with the chronically ill.
Pseudorabies Virus	(PRV) is a viral disease in swine that is endemic in most parts of the world. It is caused by <i>porcine herpesvirus 1</i> and is also known as Aujeszky's disease, and in cattle as mad itch.
Respiratory Syncytial Virus	Virus that can cause severe lower respiratory infections in children under 2 and mild upper respiratory infections in older children and adults. Inflammation of bronchioles.
Rotavirus	Rotavirus is the most common cause of severe diarrhea among children. The incubation period for rotavirus disease is approximately 2 days. The disease is characterized by vomiting and watery diarrhea for 3 - 8 days, and fever and abdominal pain occur frequently.
<i>Salmonella choleraesuis</i>	Gram negative bacteria associated with acute gastroenteritis and septicemia. Required for Hospital Disinfectants.
<i>Salmonella schottmuelleri</i>	Gram negative bacteria associated with acute gastroenteritis and diarrhea.
<i>Salmonella typhi</i>	Gram negative bacteria associated with acute gastroenteritis and diarrhea. Causative agent for typhoid fever.
SARS	Severe acute respiratory syndrome (SARS) is a viral respiratory illness caused by a coronavirus, called SARS-associated coronavirus (SARS-CoV).
<i>Serratia marcescens</i>	Gram negative bacteria associated with urinary tract infections, meningitis and septicemia .
<i>Shigella dysenteriae</i>	Gram negative bacteria directly spread by anal/oral route of infection; indirectly (including food, hands, flies) spread by contaminated food and inanimate objects resulting in bacillary dysentery.
<i>Staphylococcus aureus</i>	Gram positive bacteria identified as a major cause of hospital acquired (nosocomial) infections. Colonizes food and secretes enterotoxins which cause food poisoning after ingestion. Causes wound infections, septicemia, endocarditis, meningitis, osteomyelitis and pneumonia. Required for Hospital Disinfectants.
<i>Streptococcus faecalis</i> (Enterococcus)	Gram positive (Enterococci) bacteria causing hemolysis, urinary tract infections and endocarditis.
<i>Streptococcus pyogenes</i> (Enterococcus)	Gram positive (Enterococci) bacteria causing hemolysis, urinary tract infections and endocarditis. Causative agent of pharyngotonsillitis (sore throats).
<i>Trichophyton mentagrophytes</i>	Athlete's foot fungus. Found in shower and dressing rooms.
Vaccinia	Lipophilic (enveloped) DNA poxvirus; causes poxvirus infections.
<i>Vibrio cholerae</i>	Gram negative, rod shape bacteria; causative agent for cholerae – causes severe diarrhea -- often fatal.

<sup>5</sup> Microbiology, D. Kingsbury and G. Wagner