The Significance of a General Virucide Claim Based Upon the Efficacy Against the Polio Virus

Therapeutic Products Programme
Guidelines

DISINFECTANT DRUGS

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APPENDIX II: Evaluation Criteria

Claim[1]	Device or Surface[2]	Efficacy[3]
Chemical Sterilant or Sporicide	Any device or surface	CGSB (AOAC) Sporicidal Test [4,5,6]
Tuberculocide	Semi-critical devices	CGSB (AOAC) Tuberculocidal Test [4,5,6]
	Non-critical devices or environmental surfaces in health care facilities.	CGSB (AOAC) Tuberculocidal Test [4,5,6]
Virucide	Semi-critical devices	CGSB Testing of Virucides (Polio I virus) [4,5].
	Non-critical devices and environmental surfaces in health care facilities and food premises where food is manufactured, processed or kept.	CGSB Testing of Virucides. If efficacy against Polio I has not been demonstrated, efficacy against specific viruses must be demonstrated and these viruses named on the label. Efficacy data and specific directions for use required if HIV is involved [4].
Fungicide	Semi-critical devices	CGSB (AOAC) Fungicidal Test [4]
	Non-critical devices and environmental surfaces in health care facilities and food premises where food is manufactured, processed or kept.	CGSB (AOAC) Fungicidal Test
Disinfectant	Semi-critical devices (High-level Disinfectant)	CGSB (AOAC) Sporicidal test. Chemosterilant in not more than 10 hours [4,6]. CGSB (AOAC) Tuberculocidal test. Disinfectant contact time not less than that required for tuberculocidal activity [4,6].
	Intermediate-Level Disinfectant	CGSB (AOAC) Tuberculocidal Test. Disinfectant contact time not less than that required for tuberculocidal activity [4,7].
	Non-critical devices and environmental surfaces in health care facilities (Low-level Disinfectant)	CGSB (AOAC) Use Dilution Test must demonstrate efficacy against Salmonella, Staphylococcus and Pseudomonas.
	Environmental surfaces in premises where food is manufactured, processed or kept.	CGSB (AOAC) Use Dilution Test must demonstrate efficacy against Salmonella and Staphylococcus, as a minimum.

(1) Except for the purpose of the precleaning or storage of devices before or after sterilization, only sporicidal claims are acceptable for critical devices.
(2) The type of device (e.g., Spaulding classification (7,14), Appendix I), environmental surface or area must be specified on the label, with examples, as appropriate.
(3) These criteria are not directly applicable to gaseous sterilants or disinfectants for contact lenses.
(4) Supporting data is to be submitted with the DIN application.
(5) Virucidal data to support a claim for efficacy against HIV are required to be submitted with the DIN application only if conditions of use for efficacy against HIV (e.g. contact time, temperature, dilution rate etc.) differ from conditions of use for other claims.
(6) The titre of the inoculum must be sufficient to be able to demonstrate at least a 6 log kill.
(7) The titre of the inoculum must be sufficient to be able to demonstrate at least a 4 log kill.

The pre market evaluation and screening of hard surface disinfectants provide for claims associated to the use of surrogate organizims. For example to be called an high level disinfectant you must demonstrate a 6 Log reduction against Mycobacterium terrae as well as demonstrating through extended contact times you are effective against Bacillus subtillis and Clostridium sporogenes spores. The principle is that Mycobacterium terrae is a “gold standard” for determining broad based germicidal performance for use on those items that are classified as semi critical medical devises. A General Virucide claim employs the same principle. Polio is the representative organism for all viral pathogens. Given its resistance to germicides it is the “gold standard” for all viruses much in the same way Mycobacterium Terre is the surrogate for high-level disinfectants. The guidelines for the determination of germicidal claims are published by Health Canada.

You will note that if you do not demonstrate performance against the Poliovirus then it is required that you test and demonstrate performance against specific pathogens. So if the disinfectant can’t kill Polio you need to test each virus

Table 6

The activity of a 1:16 dilution of AHP against Salmonella cholerasuis.

Product Lot Number	Contact Temperature	Contact Line	CFU/Control carrier	CFU/test carrier	Log_{10} Reduction
007	20°C	3 min	$3.86x10^6$	0	>6
008			$3.86x10^6$	0	>6
009			$2.38x10^6$	0	>6
007	4°C	10 min	$1.65x10^6$	0	>6
008			$1.65x10^6$	0	>6
009			$2.38x10^6$	0	>6
007	45°C	1 min	$1.16x10^6$	0	>6
008			$1.16x10^6$	0	>6
009			$1.11x10^6$	0	>6

Table 7

The activity of a 1:16 dilution of AHP with an anti-foam against three types of vegetative bacteria after a contact time of one minute at 45°C*.

Test organism	CFU/Control carrier	CFU/test carrier	Log_{10} Reduction
Pseudomonas aeruginosa	$2.27x10^6$	0	>6
Staphylococcus aureus	$1.40x10^6$	0	>6
Salmonella choleraesuis	$1.11x10^6$	0	>6
*Lot#009 was tested in these experiements			

Table 8

The activity of a 1:16 dilution of AHP against Poliovirus type 1 (Sabin) at 20°C with a contact time of five minutes.

Product Lot Number	Input control	PFU/control carrier	PFU/test carrier	Log_{10} Reduction
007	$8.3x10^{66}$	$8.7x10^4$	1.34	4.8
008	$8.3x10^6$	$8.7x10^4$	1	4.9
009	$8.3x10^6$	$8.7x10^4$	10	3.94

As per the testing standards Canadian General Standards Board CAN/CGSB –2.161-97 to demonstrate efficacy against viruses you must demonstrate a 3 Log reduction. This is also very important to bring to your attention. Accelerated Hydrogen Peroxide not only kills Polio in 5 Min it does so to almost 2 Logs beyond the testing requirement.