Expertise on the virucidal efficacy of Sekusept aktiv according to EN 14476

Summary

Sekusept aktiv was tested for its virucidal efficacy according to the test methodology of EN 14476. Sekusept aktiv fulfilled the pass criteria of this standard and can therefore be claimed, to be

virucidal according to EN 14476:2013 at a concentration of 1% with a contact time of 60 min and at a concentration of 2% with a contact time of 10 min.

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Introduction

Sekusept aktiv is a peroxyacetic acid based disinfectant for medical instruments.

Test method and test parameters

Test were run according to the methodology of EN 14476 (2005)[1)].
Since the concentration of peroxyacetic acid at the end of use dilution shelf life has been determined, to be 1000 mg/kg for the 2% use solution and 600 mg/kg for the 1% use dilution, these tests were run at a concentration of approximately this concentration (1025 and 625 mg/kg respectively).

EN 14476 was revised in 2013 and the new standard states in the foreword: "Data obtained using the former version of EN 14476 may still be used." The revision introduced a new test virus, the murine Norovirus. Data with this new virus were generated in addition to the old data[3)].

Results

The following table gives the log reduction achieved against the three test viruses according to EN 14476.

Test virus / test method	Log-reduction at contact time			
	Organic soil	Concentration (mg/kg)	10 min	60 min
Polio / EN 14476	Low (0.03% bovine serum albumine)	1025	4.375	Nd
	High (0.3% bovine serum albumine + 0.3% erythrocytes)	1025	3.75	Nd
	Low (0.03% bovine serum albumine)	625	Nd	5.375
	High (0.3% bovine serum albumine + 0.3% erythrocytes)	625	Nd	≥5.5
Adeno / EN 14476	Low (0.03% bovine serum albumine)	1025	≥4.0	Nd
	High (0.3% bovine serum albumine + 0.3% erythrocytes)	1025	≥4.0	Nd
	Low (0.03% bovine serum albumine)	625	Nd	≥4.0
	High (0.3% bovine serum albumine + 0.3% erythrocytes)	625	Nd	≥4.0
Murine Norovirus EN 14476	Low (0.03% bovine serum albumine)	1000	>4.9	Nd
	High (0.3% bovine serum albumine + 0.3% erythrocytes)	1000	>4.9	Nd
	Low (0.03% bovine serum albumine)	600	Nd	>4.9
	High (0.3% bovine serum albumine + 0.3% erythrocytes)	600	Nd	>4.9

Nd = not done

Conclusion

Pass criterion according to the methodology used here is the achievement of a log reduction ≥4. Under dirty conditions at 10 min contact time only a 3.75 log reduction was detected against Polio. However, considering the confidence interval of 0.5 log, reduction would meet the 4 log requirement based on the acceptable tolerance of ½ K_{RF} (=0.25 log). Also these results were generated at a concentration representing end of use dilution shelf life, hence giving an acceptable margin of safety.

It is therefore reasonable, to state **virucidal efficacy of Sekusept aktiv according to EN 14476:2013 at a concentration of 2% with a contact time of 10 min and at a concentration of 1% with a contact time of 60 min**. This is valid over the full use dilution shelf life.

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1) Report 08.00771, Henkel Corporate Scientific Services, Mocrobiology
2) Report 14-02196, Henkel Corporate Scientific Services, Mocrobiology