

Decon 90: Certificate of Analysis

Product	Decon 90
Laboratory Reference Number	00188082
Manufacturer	Decon Laboratories Limited Conway Street, Hove, East Sussex
Date of receipt	06 March 2001
Storage conditions	Room temperature
Active substance(s)	Not known
Test method and its validation	
Method	Dilution-neutralization
Neutralizer	30g/l Polysorbate 80, 3.0 g/l Lecithin in phosphate buffer pH 7.0 ± 0.2, sterilized in the autoclave
Experimental conditions	
Period of analysis	02 May 2001 - 04 May 2001
Product test concentrations	2 ml/l, 4 ml/l, 8 ml/l
Test temperature	20°C ± 1°C
Contact time	60 min
Temperature of incubation	36°C ± 1°C

Test organism	Bacterial test suspension count	Bacterial suspension count N_v	Neutralizer Toxicity Control	Dilution Neutralizer Control
<i>Pseudomonas aeruginosa</i>	2.5 x 10 ⁸	1.4 x 10 ³	126	148
<i>Staphylococcus aureus</i>	1.9 x 10 ⁸	1.5 x 10 ³	105	78
Acceptance criteria met	Yes	Yes	Yes	Yes
Acceptance criteria	1.5 x 10 ⁸ to 5.0 x 10 ⁸	6 x 10 ² to 3 x 10 ³	≥0.05 N_v	≥0.05 N_v

The neutralization is validated with the neutralizer tested for the concentration of 8ml/l of product as received and for the two strains tested.

Test organism	Mean Viable Counts (cfu/ml) for test mixture at concentrations:		
	2.0% v/v	4.0% v/v	8.0% v/v
<i>Pseudomonas aeruginosa</i>	<150	<150	<150
<i>Staphylococcus aureus</i>	1595	<150	<150
Reduction in viability at test concentration	2.0% v/v	4.0% v/v	8.0% v/v
<i>Pseudomonas aeruginosa</i>	5.2	5.2	5.2
<i>Staphylococcus</i>	4.1	5.1	5.1

Conclusion

According to EN 1040: 1997 product Decon 90 possesses bacterial activity for the referenced strains of *Pseudomonas aeruginosa* ATCC 15442 at 2%, 4% and 8% and *Staphylococcus aureus* ATCC 6538 at 4% and 8%. In order to qualify the product as an antiseptic and/or chemical disinfectant for a defined purpose, it will be evaluated using additional standard tests