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Our References	Date
Dr. Fä./be	23. April 1998

EXPERT REPORT ON THE SERVICE LIFE

of the preparation

Korsolex® Rapid

On 06.03.1998, you commissioned us to subject your preparation ***Korsolex® Rapid*** to microbiological testing to determine whether the bactericidal effect of the preparation is given in the "Test under Simulated Conditions of Use with Rubber Tubing as the Carrier" after standing for several days without protein burden.

Method:

It was tested:

Korsolex® Rapid

with the Lot-No.: 44615113

in a concentration of 2.0 % and with 60 minutes contact time
in a concentration of 3.0 % and with 30 minutes contact time, and
in a concentration of 4.0 % and with 15 minutes contact time

according to the guidelines for "Testing and Evaluating Chemical Disinfection Procedures (Date: 12.07.1991)" of the German Society for Hygiene and Microbiology, "II. 3c) Testing under Simulated Conditions of Use with Rubber Tubing as the Carrier". The Korsolex® Rapid dilutions were prepared with water of standardised hardness (WSH) without addition of protein. The 0.5 % albumin burden required for the DGHM test was always weighed out and added immediately before the test was begun.

In one test series
with test solutions that were prepared for use for disinfection and stored for 21 days and then used to evaluate the service life.

The efficacy was determined after the solutions had been standing for 5, 7, 10, 14 and 21 days.

Test organisms:	Staphylococcus aureus	ATCC 6538
	Pseudomonas aeruginosa	ATCC 15442

Carriers:

Pieces of unused rubber tubing 1 cm in length with an inner diameter of 6 mm and a wall thickness of 2 mm. The pieces were boiled for 10 minutes in doubly distilled water and then dried.

Contamination of the pieces of tubing:

For contamination of the pieces of tubing, CLS-cultures of the test bacteria were used to which defibrinated bovine blood had been added shortly before in a final concentration of 20 %. Subsequently, the carriers were stored upright in an incubator on sterile filter paper for 4 hours at 36 ± 1°C.

The colony numbers of the suspensions (CLS + bovine blood) were determined by means of surface cultures on CSA.

Neutralizers: 3.0 % Tween 80 + 3.0 % saponin + 0.1 % histidine + 0.1 % cystei

Test procedure:

Three pieces of tubing per contact time were placed in a dish and 30 ml of disinfectant solution of the corresponding concentration containing 0.5 % bovine albumin poured on them. After the respective contact times, the three pieces of tubing were removed and rinsed separately in 10 ml of CSL plus neutralizers. Then the pieces of tubing were placed in separate culture tubes containing 10 ml of CSL plus neutralizers and incubated for 7 days at 36 ± 1°C. Carriers stored in WSH that were treated identically after the respective contact times served as the controls. The pieces of tubing were prepared fresh for each test day.
The tests were conducted with disinfectant solutions prepared on day 1.

Results:

The results are listed in the enclosed table.

After standing for 21 days, the preparation ***Korsolex® Rapid*** showed a bactericidal efficacy against the test bacteria Staphylococcus aureus and Pseudomonas aeruginosa according to the criteria of the "Guidelines for Testing and Evaluating Chemical Disinfectants (Date: 12.07.1991) II. 3c) Testing under Simulated Conditions of Use with Rubber Tubing as the Carrier" of the Germany Society for Hygiene and Microbiology

in a concentration of 4.0 % and with 15 minutes contact time,
in a concentration of 3.0 % and with 30 minutes contact time and
in a concentration of 2.0 % and with 60 minutes contact time.

(Dr. W.U. Färber)

Table: Testing under simulated conditions of use with rubber tubings (II.3.c)
at standing times of up to 28 days with burden
The required 0.5 % albumin burden was always weighed out and added immediately before the test was begun
Preparation: ***Korsolex® Rapid***

			Standing time in days			
Test organism	**Preparation concentration / Contact time in minutes**	**5**	**7**	**10**	**14**	**21**
Staphylococcus aureus ATCC 6538 Log CFU/ml		9.17	9.11	9.20	9.30	9.14
	4.0 / 15	000	000	000	000	000
	3.0 / 30	000	000	000	000	000
	2.0 / 60	000	000	000	000	000
	WSH	+++	+++	+++	+++	+++
Pseudomonas aeruginosa ATCC 15442 Log CFU/ml		9.18	9.20	9.24	9.16	9.19
	4.0 / 15	000	000	000	000	000
	3.0 / 30	000	000	000	000	000
	2.0 / 60	000	000	000	000	000
	WSH	+++	+++	+++	+++	+++

Legend:
+ = growth of organisms detected
o = no growth of organisms detected
WSH = Water of standardized hardness
n. d. = not done