

Schülke & Mayr GmbH

Robert-Koch-Str. 2

22851 Norderstedt

Deutschland / Germany

CUSTOMER NUMBER

249

DATE

March 08, 2016

REPORT A 15317-2

THERMOSEPT ED

TUBERCULOCIDAL AND MYCOBACTERICIDAL EFFICACY

(EN 14348)

Purpose

The tuberculocidal and mycobactericidal activity of **Thermosep ED** (Schülke & Mayr GmbH, Norderstedt, Germany) as an instrument disinfectant should be evaluated at a process temperature of 55 °C in accordance with the European Standard **EN 14348 (2005)**.

Test description

Manufacturer:	Schülke & Mayr GmbH, Norderstedt, Germany		
Product name:	Thermosept ED		
Batch number:	1234401		
Manufacturer date:	05/2013		
Best before:	04/2016		
Sample number:	P 157049		
Storage conditions:	Room temperature		
Product dilution:	hard water		
Date of order:	December 08, 2015		
Date of delivery:	December 08, 2015		
Test date:	January 14, 2016 – March 08, 2016		
Basis:	EN 14348 (2005): Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)		
Test organisms:	<i>Mycobacterium terrae</i>	ATCC 15755	
	<i>Mycobacterium avium</i>	ATCC 15769	
Test solution:	2 %, 1 %, 0.5 %, 0.1 %, 0.01 %		
Active ingredients in 100 g:	20 % Glutaral 5 – 15 % Ethanol		
Odour:	product specific		
Appearance:	clear, colourless liquid		
Appearance of test solutions:	clear, colourless solutions		
pH value:	100 %: 3.45	1 %: 6.41	0.5 %: 6.60
	0.1 %: 7.04	0.01 %: 7.06	WSH: 7.07
Neutralizer:	3 % Tween80 + 2 % Histidine + 0.3 % Lecithin + 2 % Glycine (Neutralizer XLVII)		
	3 % Tween80 + 0.1 % Histidine + 0.3 % Lecithin + 2 % Glycine (Neutralizer XXI, for <i>M. avium</i> , only)		
Interfering substance:	0.03 % albumin (clean conditions)		
Test temperature:	55 ± 1 °C		
Incubation temperature:	36 ± 1 °C		

Test Method

Testing is based on the European Standard EN 14348 (2005). Validation and control procedures are therefore carried out in accordance with that standard, too.

For the test, to a sample of the product **Thermosep ED** (diluted with hard water if necessary) is added to a suspension of test organisms in a solution of the interfering substance. In deviation of the EN 14348 standard test temperature, the mixture is maintained at 55 ± 1 °C for the required contact time. At the end of the contact time, an aliquot of 1 ml is taken; the microbicidal activity in this portion is immediately neutralized. Two 1 ml samples (per dilution step) of the resulting suspension are spread on at least 2 plates each. The number of surviving test organisms in the test mixture is calculated for each sample and the reduction is determined with respect to the corresponding test suspension N_0 .

The experimental conditions (control A), the non-toxicity of the neutralizer (control B) and the dilution-neutralization method (control C) are validated in accordance with the EN 14348. The test is performed under clean conditions using *M. terrae* and *M. avium* as test-organisms. Result are presented in tables 1.1. – 2.3.

Results

According to the EN 14348 (2005), the product **Thermosep ED**, when applied at the concentration of at least 0.1 %, possesses **tuberculocidal efficacy** ($\log_{10} RF \geq 4$) in 5 min under at 55 °C under **clean conditions** for reference strain *M. terrae* (Tab. 1.1 – 1.2).

According to the EN 14348 (2005), the product **Thermosep ED**, when applied at the concentration / contact time - relation of at least 0.5 % / 5 min at 55 °C, possesses **mycobactericidal efficacy** ($\log_{10} RF \geq 4$) under **clean conditions** for reference strains *M. terrae* and *M. avium*. (Tab. 1.1 - 2.2.2).

Results are validated in accordance with the requirements of the EN 14348 (2005).

Greifswald, March 08, 2016


Dr. rer. med. (Dipl. Biol.) T. Koburger-Janssen
- General Manager -


Prof. Dr. med. A. Kramer
- MD for Hygiene and Environmental Medicine -