

MINISTRY OF DEFENCE
OF THE RUSSIAN FEDERATION
PRINCIPAL MILITARY
CLINICAL HOSPITAL
Named after N.N. Burdenko
Hospitalnaya Sq., 3
Moscow 105229
July 27, 2005
No 8\ 233

DIRECTOR GENERAL OF
LLC Research and Development Company
“Sabina –Grand”

Head of Principal Military
Medical Department of
the Ministry of Defense
of the Russian Federation
Moscow. K-160

We are sending the protocol of clinical approbation of disinfectant detergent “Sabisept M”.
Enclosure: 2 copies of the protocol consisting of 5 pages each; one for the first address, the
other for the second address.

HEAD OF THE HOSPITAL
Major General of Medical Service
V.M. Klyuzhev

“Approve”

Head of the Principal Military Clinical Hospital
named after N.N. Burdenko
MD, PhD, professor
V.Klyuzhev
July 2005

PROTOCOL

Of approbation of disinfectant detergent “SABISEPT M”
(LLC Research and Development Company “Sabina –Grand, Russia)
Grounds: permission of Principal Military Medical Department

Within the period from June 27 to July 27 on the base of sanitary epidemiological, central sterilization and surgical departments of the Principal military clinical hospital named after N.N. Burdenko there was carried out an approbation of the disinfectant detergent “SABISEPT M” (LLC Research and Development Company “Sabina –Grand) for assessment of its consumer properties with objective methods of analysis.

LLC Research and Development Company “Sabina –Grand (Russia) has provided the hospital with 1litre of the detergent in standard package.

The normative documents for correspondence to safety and efficiency in accordance with the State Standard 12.1.007-96 “The list of normative parameters of disinfection, disinsection and deratization detergents which are under control and obligatory certification” p.1.1, 2.1., No 01-12/75, approved by Russian State Committee of Sanitary Epidemiological Supervision in February 5, 1996.

The normative documents for methods of analysis “Digest of methods of analysis and assessment of disinfectant detergents” dated January 11, 1996, the normative documents for the use of “Instruction for Application of the detergent “SABISEPT M”” (LLC Research and Development Company “Sabina –Grand, Russia) in medical and preventive treatment institutions and infection foci” approved by the Director of the State Institution Central Scientific Research Institute of Epidemiology of the Russian Federation on the 17th of May, 2005.

The disinfectant detergent “SABISEPT M” was tested for several qualities: disinfection of medical items as well as surfaces and items of functional diagnostic premises of the hospital departments.

Application of the detergent for disinfection of medical items carried out in accordance with the “Instruction for application...” revealed efficient level of disinfectant capacity of the detergent “SABISEPT M” in relation to micro flora contaminating instruments after its use.

After disinfection the micro flora on medical items was not revealed. 146 tests was carried out.

Reaction to latent blood (azopyrame test) in all tests was negative. There were carried out 108 tests. The results are presented in Table 1.

Disinfectant properties of the detergent “SABISEPT M” while surfaces disinfection were assessed with the following methods:

1. Application of suspensions of cultures of hospital strains (E.Coli, St. aureus. Ps. aeuginosa) prepared in accordance with turbidity standard on different test-objects with further disinfection.
2. Disinfection of deliberately sown objects of the environment of functional diagnostic premises of the hospital departments.

The carried out tests revealed sufficient efficiency of the disinfectant action of the tested detergent in relation to the studied bacterial flora (including hospital polyantibiotic resistant strains of gram-positive and gram-negative bacteria). Concentration and the time of exposition were chosen in accordance with “Instruction for application ...” of the detergent. The research consisted of 340 sanitary microbiological tests. The results are presented in tables 2 and 3.

During the approbation of the detergent “SABISEPT M” the following extra positive properties characterizing its consumer qualities were revealed:

- Low toxicity, the lack of allergic reactions, irritating effect on respiratory organs, hand skin and mucous membrane;

- The presence of washing properties of the detergent;
- High disinfectant activity in relation to hospital strains of gram-positive and gram-negative bacteria;
- Lack of fixing action of working solutions of the detergent;
- Detergent solutions do not cause corrosion of metal, instruments and glassware is easily purified from biological admixtures;
- Possibility of long term use of the detergent working solutions;
- Deodorizing effect;
- Possibility of using the detergent working solutions in patients' presence;
- The disinfectant solutions do not interact with surfaces, coverings and do not leave stains;
- Economy of using the detergent.

CONCLUSION:

As a result of approbation sufficient disinfectant capacity of the detergent "SABISEPT M" for disinfection of surfaces and objects of functional diagnostic premises, medical items was identified (LLC Research and Development Company "Sabina –Grand, Russia).

The disinfectant detergent "SABISEPT M" (LLC Research and Development Company "Sabina – Grand, Russia) is recommended for use in medical and preventive treatment institutions of the Ministry of Defense of the Russian Federation.

Taking into account the wide range of antimicrobial action of the detergent "SABISEPT M" and extra properties of this disinfectant it is essential to recommend it for using in preventive (anti-epidemiological) activities in war time and during local military conflicts.

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