

FEDERAL SERVICE FOR SUPERVISION IN THE SPHERE OF CONSUMER RIGHTS PROTECTION AND HUMAN WELL-BEING

CERTIFICATE OF STATE REGISTRATION

No 77.99.36.2.Y.4661.6.08 dated June 5, 2008

In accordance with the Federal Law dated March 30, 1999 No 52-Φ3 "On Sanitary-Epidemiological Well-Being of the Population" the product

(Name of the product, substance, pharmaceutical, name and legal address of the manufacturer, sphere of application):

Disinfectant detergent "Sabisept M" (Specifications 9392-001-74518126-2005 "Disinfectant detergent "Sabisept M" with notifications of changes in Specifications dated May 16, 2008 No1 dated May 16, 2008 No 2); product is produce by CJSC "Klin-Cosmetics", 88 km, Leningradsky Av., town of Klin, Klinsky district, Moscow region, 141600 in accordance with the Specifications, formulation, technical regulations developed by LLC Research and Development Company "Sabina –Grand", Office 202, Building 20/30, Structure 5, Krzhizhanovskogo Str., Moscow, 117218, the Russian Federation; sphere of application is in accordance with instructions dated May 17, 2005 No 1 on applying the detergent in medical and preventive treatment institutions and foci of infections; dated May 17, 2005 No 2 on applying the detergent for preventive disinfection at municipal enterprises, educational establishments, cultural, leisure, sport, and social maintenance, child welfare institutions; dated May 16, 2008/ No 3/08 on applying the detergent for disinfection of the railway and subway objects.

has been registered, recorded in the State Registry and has the permission for production on the territory of the Russian Federation, import to the territory of the Russia Federation and turnover.

The present certificate is issued

Instead of the certificate of state registration No 77.99.36.2.Y.14142.12.06 dated December 21, 2006; on the basis of expert reports on the results of disinfection expertise dated December 14, 2006 No 3-05/1010, dated May 16, 2008 No 3-05/373 Federal State Institution of Science "Scientific Research Institute of Disinfectology" by Rospotrebnadzor; dated May 16, 2008 No 01/081/369 Federal State Unitary Enterprise All-Russian Scientific Research Institute of Railway Hygiene of Rospotrebnadzor; information about safety measures while production, turnover and application (use) are stated in Specifications 9392-001-74518126-2005 with notifications about changes in Specifications dated May 16, 2008 No 1, dated May 16, 2008 No 2 and instructions for application; dated May 17, 2005 No 1, dated May 17, 2005 No 2, dated May 16, 2008 No 3/08.

The certificate is valid for the whole period of production of the Russian products and supply of import products.

Head (Vice-Head) of the Federal Service for
Supervision of Consumer Rights Protection and
Human Well-Being

/signature/ G.G. Onishchenko
/full name/

Seal: Federal Service for Supervision of Consumer Rights Protection and Human Well-Being, Principal State
Registration Number 1047796261512

No 0055747
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REVIEWED BY:

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May 17, 2005

Seal: Ministry of Public Health of the Russian
Federation, Scientific Research Institute of Dis-
infectology of the Ministry of Public Health of
the Russian Federation, Principle State Registra-
tion Number 1027739534396/

APPROVED BY:

Director General
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May 17, 2005
Seal: Limited Liability Company Research De-
velopment Company "Sabina-Grand", Principle
State Registration Number 1047798807211

INSTRUCTION No1
for the use of disinfectant "Sabisept M"
(LLC Research Development Company "Sabina-Grand", Russia)
at medical and preventive treatment institutions and foci of infections

Moscow
2005

INSTRUCTION No1
for the use of disinfectant “Sabisept M”
(LLC Research Development Company “Sabina-Grand”, Russia)
at medical and preventive treatment institutions and foci of infections

The instruction is developed by Scientific Research Institute of Disinfectology (SRID) of the Ministry of Public Health of the Russian Federation,

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General Information

1.1. Detergent «Sabisept M» is a transparent colorless or yellow liquid. It contains the following active agents: alkyldimethylbenzylammonia chloride (ADBC) – 12% and basic nitrile – 3.5%, besides, it includes neonol and other components. pH 2% of the detergent solution – 5.6 – 8.0.

Storage life of the detergent in the open producers' package is 5 years, working solutions – 14 days provided that they are stored in a closed package.

The detergent is produced in polymer bottles of 1 dm³ and containers of 3 and 5 dm³.

1.2. The detergent “Sabisept M” has counter bacillicidal (including tuberculocide), virucidal and fungicide (in regard to fungi of the following types: Candida, Trichophyton, Aspergillus) activity and washing properties.

1.3. The detergent “Sabisept M” in regard to the parameters of acute toxicity in accordance with the State Standard 12.1.007-76 on injection into the stomach is referred to the third class of moderately hazardous substances, on applying onto the skin it is referred to the fourth class of low hazardous substances; on injection to the abdomen it is referred to the fourth class of practically non-toxic substance in accordance with classification by K.K. Sidorov. In regard to fugacity the vapor of the detergent and working solutions on one-time inhalant effect is low-hazardous. The detergent produces local irritating effect on the skin and evident effect on conjunctiva and has weak sensobilizing effect.

Working solutions in the form of aerosol and vapor cause irritation of mucous coat of upper respiratory passages. The area of acute toxic action is ≤ 1 .

Maximum allowable concentration (MAC) in the air of the working zone for alkyldime-tilbenzylammonia chloride is 1 mg/m³

MAC in the air of the working zone for the basic nitrile is 2 mg/m³.

1.4. The detergent «Sabisept M» is used for:

- Disinfection of surfaces in premises, devices and equipment surfaces, solid furniture surfaces; disinfection of sanitary technical equipment, cleaning devices, rubber mats, rubber footwear, plastic and polymer materials; disinfection of the items for patient care, personal care items, toys (except for soft toys), linen (including disposable), tableware and glassware, medical items for one-time use and textile medical wastes (tissues, tampons, bandage material and so on) before utilization in cases of infections of bacterial (including tuberculosis) and viral etiology, candidosis and dermatomycosis on preventive, current and final disinfections in medical and preventive treatment institutions, child welfare institutions, foci of infections;
- Disinfection at sanitary transport;
- Clear-out;
- Processing of the surfaces in the premises to remove moulds;
- Disinfection and pre-sterilization cleaning, including the cases when medical items (surgical and dental ones) rigid and flexible endoscopes and other instruments are combined in one process; preliminary cleaning of rigid and flexible endoscopes and other instruments; final cleaning of rigid and flexible endoscopes before disinfection of higher level (DHL) of rigid and flexible endoscopes.

2. Preparation of the Detergent Working Solutions

Working solutions of the detergent are prepared in the flasks made of any material by adding the corresponding quantity of the detergent “Sabisept M” to drinking (tap) water of room temperature (Table 1).

Table 1 - Preparation of the Detergent Working Solutions

Concentration of the working solution (%) for:			The number of components (ml) necessary for the preparation of the working solution of the following volume:			
Detergent	Active agents		1 litre		10 litres	
	ADBC	amine	Detergent	Water	Detergent	Water
0.1	0.012	0.0035	1	999	10	9990
0.2	0.024	0.007	2	998	20	9980
0.5	0.06	0.017	5	995	50	9950
1.0	0.12	0.035	10	990	100	9900
1.5	0.18	0.052	15	985	150	9850
2.0	0.24	0.07	20	980	200	9800
3.0	0.36	0.10	30	970	300	9700
4.0	0.48	0.14	40	960	400	9600
5.0	0.6	0.17	50	950	500	9500
10.0	1.2	0.35	100	900	1000	9000

3. Application of Solutions of the Detergent «Sabisept M»

3.1. Solutions of the detergent «Sabisept M» are used for:

Disinfection of surfaces in premises, devices and equipment surfaces, solid furniture surfaces; disinfection of sanitary technical equipment, cleaning devices, rubber mats, rubber footwear, plastic and polymer materials; disinfection of the items for patient care, personal care items, toys (except for soft toys), linen (including disposable), tableware and glassware, medical items for one-time use and textile medical wastes (tissues, tampons, bandage material and so on) before utilization; disinfection at sanitary transport; clear-out;

Disinfection and pre-sterilization cleaning, including the cases when medical items (surgical and dental ones) rigid and flexible endoscopes and other instruments are combined in one process; preliminary cleaning of rigid and flexible endoscopes and other instruments; final cleaning of rigid and flexible endoscopes before disinfection of higher level (DHL) of rigid and flexible endoscopes.

Modes of disinfections of the objects in cases of different infections are presented in tables 2-7; disinfection combined with pre-sterilization cleaning of medical items including endoscopes and their tools are presented in tables 9-14. Premises clear-outs are carried out in accordance with the modes stated in table 8.

3.2. Surfaces in premises (floor, walls and others), surfaces of devices, equipment, solid furniture surfaces, sanitary transport are rubbed with waste cloth moistened with the detergent solution or watered from a hydraulic sprayer, an automax or an atomizer of “Quazar” type. The norm of detergent consumption in case of wiping – 100 ml-m²; in case of watering – 300 ml-m² (a hydraulic sprayer, an automax), 150 ml/l m² (an atomizer of “Quazar” type). After cleaning the premises with the detergent they should be aired.

After spraying the premises with the detergent wet cleaning should be organized.

To struggle against mould in the premises, all surfaces should be cleaned with 10% solution of the detergent, then with the solution of the same concentration one more time. Disinfection retention time is 120 minutes; for prevention of mould growth surfaces are wiped with 10% solution of the detergent once a month.

3.3. Sanitary technical equipment (baths, sinks and so on) are processed with the detergent solution with a brush or bristle brush with an average solution consumption - 200 ml/m² or sprayed with a hydraulic sprayer, an automax (consumption of working solution – 300 ml/m²) or an atomizer of “Quazar”

type (150 ml/m²). Rubber mats are disinfected by wiping or immersion into the detergent solution. After disinfection sanitary technical equipment is washed with water.

3.4. Items for patient care are immersed into the detergent solution or wiped with waste cloth moistened with the detergent solution. After disinfection they are thoroughly washed with water for 3 minutes.

3.5. Small toys are completely immersed into the container with the detergent solution preventing them from rising onto the surface; the large ones are wiped with waste cloth or sprayed with the detergent solution. After disinfection they are washed with flowing drinking water.

3.6. Footwear of rubber, plastic and other polymer materials are immersed into 2% detergent solution for 90 minutes, after this they are washed with flowing drinking water for 3 minutes.

3.7. Tableware free of food wastes is immersed into the detergent. The solution consumption should therewith be 2 litres per one set of tableware, after this they are washed with flowing drinking water for 3 minutes.

3.8. Linen is immersed in the container with detergent solution. The solution consumption should therewith be 5 litres per one kg of dry linen. The container is covered with the top. After disinfection the linen is washed and rinsed.

3.9. Cleaning equipment is immersed into the detergent solution. After this it is washed with water.

3.10. Medical wastes (used bandage material, cotton and gauze tissues, cotton tampons) are collected into a separate container with the detergent solution, after disinfection retention they are disposed of.

3.11. Medical items and disposable linen are soaked into detergent solution, and when the retention time is over, they are disposed of.

3.12. Disinfection and pre-sterilization cleaning (including cases when they are combined) are carried out in plastic, enameled (enamel should not be damaged) containers covered with tops. Items are immersed into working solution of the detergent. Dismountable details are to be immersed when divided. Items having locking parts are immersed unlocked but before this one should make several locking movements in the solution for its better penetration into hard-to-reach areas. While disinfection retention time channels and cavities are to be filled in (without airlocks) with the detergent solution. Thickness of the solution layer should be no less than 1 cm.

After items processing they are washed with flowing water for 3 minutes.

The temperature of working solutions should be no less than plus 18°C.

Working detergent solutions should be applied for disinfection and pre-sterilization cleaning including cases when they are combined in one process many times but within 14 days at most if they look the same. If the first signs of changes in appearance occur (changes in colour, solution turbidity, and so on), the solution should be changed.

Quality of pre-sterilization cleaning is checked by performing an azo-pyram or amidopyrine tests for residual blood quantity.

Azo-pyram tests are carried out in accordance with methodological instruction "Quality control of pre-sterilization cleaning of medical items with azopyram agent" (No 28-6/13 dated May 25, 1988), amidopyrine tests – in accordance with the method stated in "Methodological Instruction for pre-sterilization cleaning of medical items" (No 28-6/13 dated June 8, 1982).

1% of simultaneously processes items of one name (but no less than three items) is to be under control.

In the event some blood residuals are found (positive tests), all group of items among which there are the items for control is to be repeatedly processed before obtaining the negative result.

3.13. Disinfection of endoscopes and their tools as well as their cleaning before the stated procedures is carried out in accordance with the requirements of sanitary epidemiological regulations CII 3.1.1275-03. «Prevention of Infectious Diseases while Endoscope Procedures».

Preliminary cleaning of endoscopes and their instruments are carried out in accordance with paragraphs 4.1.1.-1.4. CII 3,1,1275-03 using 0.1% (of the detergent) of the detergent solution.

3.14. Disinfection of endoscopes and their instruments including combined cleaning with their pre-sterilization or final cleaning of endoscopes before disinfection of higher level, after application by infectious patient in accordance with the mode recommended for the corresponding infection taking into account the requirements of anti-epidemiological mode for inflectional in-patient department.

Table 2 - Modes of Disinfection of the Objects with Solution of the Detergent "Sabisept M" in Cases of Bacterial Infections (except for Tuberculosis)

Object for disinfection	Solution concentration (in accordance with the detergent), %	Disinfection time, min	Mode of disinfection
Surfaces in the premises, surfaces of devices, equipment, solid furniture surfaces, sanitary transport	0.1	60	Wiping
	1.0	60	Spraying
Sanitary technical equipment	0.1	90	Wiping
	1.0	60	Spraying
Tableware free of food wastes	0.2	60	Immersion
	0.5	15	
Tableware with food wastes	1.0	60	Immersion
Not dirty linen	0.2	60	Soaking
	0.5	30	
Linen soiled with faeces	2.0	60	Soaking
Items for patient care not soiled with blood and other biological substrata *	0.2	60	Wiping
	0.5	30	
	0.5	60	Immersion
Glassware not soiled with blood and other biological substrata *	0.5	60	Immersion
Toys	0.2	60	Immersion
	0.5	30	
	0.5	60	Immersion
	1.0	60	Spraying
Textile medical wastes (bandage material: cotton and gauze tissues, tampons, bandages, disposable linen and other)	3.0	60	Immersion
Cleaning equipment	2.0	60	Soaking

Note: * - in case of soiling the objects with blood and other biological substrata disinfection is carried out in accordance with the mode effective for viral infections (see Table 3)

Table 3 - Modes of Disinfection of the Objects with Solution of the Detergent “Sabisept M” in Cases of Viral Infections

Object for disinfection	Solution concentration (in accordance with the detergent), %	Disinfection time, min	Mode of disinfection
Surfaces in the premises, surfaces of devices, equipment, solid furniture surfaces, sanitary transport	1.0	60	Wiping
	2.0	60	Spraying
Sanitary technical equipment	1.0	60	Wiping
	2.0	60	Spraying
Tableware free of food wastes	0.2	60	Immersion

Tableware with food wastes	1.0	60	Immersion
Not dirty linen	0.2	60	Soaking
Linen soiled with blood	2.0	60	Soaking
Linen soiled with discharges	2.0	120	Soaking
Items for patient care	1.0	60	Immersion or wiping
Glassware	1.0	30	Immersion
Toys	1.0	60	Immersion or wiping
	2.0	60	Spraying
Textile medical wastes (bandage material: cotton and gauze tissues, tampons, bandages, disposable linen and other)	3.0	60	Immersion
Cleaning equipment	2.0	120	Soaking

Table 4 - Modes of Disinfection of the Objects with Solution of the Detergent “Sabisept M” in Cases of Tuberculosis

Object for disinfection	Solution concentration (in accordance with the detergent), %	Disinfection time, min	Mode of disinfection
Surfaces in the premises, surfaces of devices, equipment, solid furniture surfaces, sanitary transport	2.0	60	Wiping
	5.0	60	Spraying
Sanitary technical equipment	2.0	60	Wiping
	5.0	60	Spraying
Tableware free of food wastes	1.0	60	Immersion
	2.0	15	
Tableware with food wastes	3.0	60	Immersion
Not dirty linen	2.0	60	Soaking
Linen soiled with discharges	3.0	60	Soaking
Items for patient care	2.0	60	Immersion or wiping
Glassware	2.0	60	Immersion
Toys	2.0	60	Immersion or wiping
	5.0	60	Spraying
Textile medical wastes (bandage material: cotton and gauze tissues, tampons, bandages, disposable linen and other)	3.0	60	Immersion
Cleaning equipment	3.0	60	Soaking

Table 5 - Modes of Disinfection of the Objects with Solution of the Detergent “Sabisept M” in cases of Candidosis

Object for disinfection	Solution concentration (in accordance with the de-	Disinfection time, min	Mode of disinfection
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	tergent), %		
Surfaces in the premises, surfaces of devices, equipment, solid furniture surfaces, sanitary transport	0.5	120	Wiping
	1.0	30	
	2.0	60	Spraying
Sanitary technical equipment Tableware free of food wastes	0.5	120	Wiping
	1.0	30	
	2.0	60	Spraying
Tableware with food wastes	0.5	15	Immersion
Sanitary technical equipment	3.0	30	Immersion
Dirty linen	0.5	60	Soaking
	1.0	30	
Linen soiled with discharges	2.0	60	Soaking
Items for patient care	0.5	60	Immersion or double wiping with the period of 15 minutes
	1.0	60 30	Wiping Immersion
Glassware	1.5	60	Immersion
	2.0	30	
Toys	1.0	60	Wiping
		30	Immersion
	2.0	60	Spraying
Textile medical wastes (bandage material: cotton and gauze tissues, tampons, bandages, disposable linen and other)	3.0	60	Immersion
Cleaning equipment	2.0	60	Soaking

Table 6 –Modes of Disinfection of the Objects with the detergent solution “Sabisept M” in cases of derma dermatomycosis

Object for disinfection	Solution concentration (in accordance with the detergent), %	Disinfection time, min	Mode of disinfection
Surfaces in the premises, surfaces of devices, equipment, solid furniture surfaces, sanitary transport	4.0	60	Wiping
	5.0	120	Spraying
Sanitary technical equipment	4.0	60	Wiping or double spraying with the period of 15 minutes
Rubber mats	4.0	60	Wiping or Immersion
Footwear of rubber, plastic and other polymer materials	2.0	60	Immersion
Not dirty linen	3.0	30	Soaking
Linen soiled with discharges	3.0	60	Soaking
Items for patient care	2.0	60	Immersion
	4.0	60	Wiping
Glassware	1.0	90	Immersion
	2.0	60	

Textile medical wastes (bandage material: cotton and gauze tissues, tampons, bandages, disposable linen and other)	3.0	60	Immersion
Cleaning equipment	3.0	60	Soaking

Table 7 - Modes of Disinfection of the Medical Items with the Detergent Solution “Sabisept M” in cases of viral and bacterial infections (including tuberculosis) and mycotic (candidosis, dermatomycosis) etiology.

Object for disinfection	Solution concentration (in accordance with the detergent), %	Disinfection time, min		Mode of disinfection
		Viral and bacterial (including tuberculosis) infections, candidosis	Viral, bacterial (including tuberculosis) and mycotic (candidosis, dermatomycosis) infections	
Medical items of different materials (including disposable items before utilization)	1.5 2.0	60 30	- 60	Immersion
Endoscopes, instruments to endoscopes	2.0	30		Immersion with pumping channel

Table 8 - Modes of Disinfection of the Objects with the Detergent Solution “Sabisept M” in cases of clean-outs in medical and preventive treatment institutions and child welfare institutions.

Institution profile	Solution concentration (in accordance with the detergent), %	Disinfection time, min	Mode of disinfection
Surgical departments, procedure rooms, dentistry, obstetrics and gynecological departments, class rooms, laboratories.	1.0	60	Wiping
Anti-tuberculosis medical preventive institutions	2.0	60	Wiping
Inflectional medical preventive institutions *	-	-	Wiping
Dermato-venerological preventive institutions	4.0	60	Wiping
Child welfare institutions	0.1	60	Wiping

Note: * disinfection is carried out in accordance with the corresponding infection mode

Table 9 – Modes of disinfection combined with pre-sterilization cleaning, medical items (except for endoscopes and their tools) of the detergent “Sabisept M”

Stages of processing	Modes of processing		
	Working solution concentration (in accordance with the detergent), %	Temperature of the working solution, °C	Retention time/ Processing time, min
Soaking of the items at complete immersion into the working solution of the detergent and filling in with it the channels of the items	1.5	No less than 18	60*
	2.0		30**
			60***
Washing of each item in the solution where soaking was carried out with a bristle brush, brush, cotton –gauze tampons or cloth tissue, and item channels – with a syringe: <ul style="list-style-type: none"> • items not having locking parts, channels or cavities; • items having locking parts, channels or cavities; 	In accordance with concentrations used at the stage of soaking	The same	0.5
Rinsing in flowing drinking water (channels- with a syringe or an electrical pump)	Not regulated		3.0
Rinsing in distilled water (channels- with a syringe or an electrical pump)	Not regulated		0.5

Notes:

* at the stage of soaking in the working solution there is disinfection of items in cases of viral, bacterial (except for tuberculosis) and mycotic (candidosis) infections;

** this is the mode for items not having locking parts, channels and cavities (but for dental mirrors with amalgam); at the stage of soaking in working solution there is disinfection of items in cases of viral, bacterial (except for tuberculosis) and mycotic (candidosis) infections; на

*** at the stage of soaking in the working solution there is disinfection of items in cases of viral, bacterial (including tuberculosis) and mycotic (candidosis and dermatomycosis) infections.

Table 10 – Modes of Disinfection Combined with Pre-sterilization Cleaning, Flexible and Rigid Endoscopes with the Detergent «Sabisept M».

Stages of processing	Modes of processing		
	Working solution concentration (in accordance with the detergent), %	Temperature of the working solution, °C	Retention time/ Processing time, min
Soaking * of endoscopes at complete immersion (if it is not possible – at the immersion of their parts allowed for immersion) into the working solution of the detergent and filling in with it the channels of the items .	2.0	No less than 18	30

Washing of each endoscope in the same solution where soaking was carried out: FLEXIBLE ENDOSCOPES: <ul style="list-style-type: none"> • instrumental channel is cleaned with a brush for cleaning instrumental channels; • internal channels are washed with a syringe or electric pump; • external surface is washed with gauze (cloth) tissue. RIGID ENDOSCOPES: <ul style="list-style-type: none"> • Each detail is washed with a bristle brush or gauze (cloth) tissue. • channels are washed with a syringe 	2.0	The same	2.0
			3.0
			1.0
			2.0
Rinsing in flowing drinking water (channels- with a syringe or an electrical pump)	Not regulated		3.0
Rinsing in distilled water (channels- with a syringe or an electrical pump)	Not regulated		1.0

Note: * at the stage of soaking items in working solution there is disinfection of items in cases of in cases of viral, bacterial (including tuberculosis) and mycotic (candidosis and dermatomycosis) infections.

Table 11 – Mode of Disinfection Combined with Pre-sterilization Cleaning, Instruments to Flexible Endoscopes with the solution of the detergent «Sabisept M».

Stages of Processing	Modes of processing		
	Working solution concentration (in accordance with the detergent), %	Working solution concentration (in accordance with the detergent), %	Retention time/ Processing time, min
Soaking * of instruments at complete immersion into the working solution of the detergent and filling in with it the channels of the instruments with a syringe.	2.0	No less than 18	30
Washing of each instrument in the same solution where the soaking was carried out: <ul style="list-style-type: none"> • external surface – with a brush or gauze (cloth) tissue; • internal open channels - with a syringe 	2.0	The same	2.0
			1.5
Rinsing in flowing drinking water (channels- with a syringe or an electrical pump)	Not regulated		3.0
Rinsing in distilled water (channels- with a syringe or an electrical pump)	Not regulated		1.0

Note: * at the stage of soaking items in working solution there is disinfection of items in cases of in cases of viral, bacterial (including tuberculosis) and mycotic (candidosis and dermatomycosis) infections.

Table 12 – Modes of Pre-Sterilization not Combined with Disinfection of the Medical Items (Except for endoscopes and instruments) with Solution of the Detergent «Sabisept M».

Stages of Processing	Modes of processing		
	Working solution concentration (in accordance with the detergent), %	Working solution concentration (in accordance with the detergent), %	Retention time/ Processing time, min
Soaking of the items at complete immersion into the working solution of the detergent and filling in with it the channels of the items: <ul style="list-style-type: none"> • items not having locking parts, channels or cavities (but for mirrors with amalgam); • items having locking parts, channels or cavities (but for dental forceps); • dental mirrors with amalgam and forceps 	0.1	No less than 18	10
			15
	0.2	The same	15
Washing of each item in the solution where soaking was carried out with a bristle brush, brush, cotton –gauze tampons or cloth tissue, and item channels – with a syringe: <ul style="list-style-type: none"> • items not having locking parts, channels or cavities; • items having locking parts, channels or cavities; 	In accordance with concentrations used at the stage of soaking		0.5
			1.0
Rinsing in flowing drinking water (channels-with a syringe or an electrical pump)	Not regulated		3.0
Rinsing in distilled water (channels- with a syringe or an electrical pump)	Not regulated		0.5

Table 13 – Modes of Pre-sterilization Cleaning (final cleaning before disinfection of higher level), not combined with disinfection of flexible and rigid endoscopes of the detergent solution «Sabisept M».

Stages of Processing	Modes of processing		
	Working solution concentration (in accordance with the detergent), %	Working solution concentration (in accordance with the detergent), %	Retention time/ Processing time, min
Soaking of endoscopes at complete immersion (if it is not possible – at the immersion of their parts allowed for immersion) into the working solution of the detergent and filling in the cavities and channels of the items.	0.1	No less than 18	15

<p>Washing of each endoscope in the same solution where soaking was carried out: FLEXIBLE ENDOSCOPES:</p> <ul style="list-style-type: none"> • instrumental channel is cleaned with a brush for cleaning instrumental channels; • internal channels are washed with a syringe or electric pump; • external surface is washed with gauze (cloth) tissue. <p>RIGID ENDOSCOPES:</p> <ul style="list-style-type: none"> • Each detail is washed with a bristle brush or gauze (cloth) tissue. • channels are washed with a syringe <p>Rinsing in flowing drinking water (channels- with a syringe or an electrical pump)</p> <p>Rinsing in distilled water (channels- with a syringe or an electrical pump)</p>	0.1	The same	2.0
			3.0
			1.0
			2.0
			2.0
	Not regulated		3.0
	Not regulated		1.0

Table 14 – Mode of Pre-sterilization Cleaning Not Combined with Disinfection of Instruments to Flexible Endoscopes with the Solution of the Detergent «Sabisept M».

Stages of Processing	Modes of processing		
	Working solution concentration (in accordance with the detergent), %	Working solution concentration (in accordance with the detergent), %	Retention time/ Processing time, min
Soaking of instruments at complete immersion into the working solution and filling with it open channels of instruments with a syringe.	0.1	No less than 18	15
Washing of each instrument in the same solution where the soaking was carried out:	0.1	The same	2.0
<ul style="list-style-type: none"> • external surface – with a brush or gauze (cloth) tissue; • internal open channels - with a syringe 			1.5
Rinsing in flowing drinking water (channels- with a syringe or an electrical pump)	Not regulated		3.0
Rinsing in distilled water (channels- with a syringe or an electrical pump)	Not regulated		1.0

4. Safety Measures

4.1. People under 18, people being allergic and sensitive to chemical substances should not have access to work with the detergent.

4.2. Preparation of working solutions should be carried out only in case of protecting hands with rubber gloves, and protecting eyes with hermetic glasses.

4.3. During work one should not splash solutions and avoid contact with the skin and eyes.

4.4. Works involving wiping with working solutions can be carried out without protection of respiratory organs and in patients' presence. Hand skin should be protected with rubber gloves.

When processing the surfaces with the detergent solutions by spraying, the personnel should use individual protection equipment for respiratory organs – multifunctional respirators of the types ПИГ-67 или РУ-60М with the plug of B type, for eyes – hermetic glasses, for hand skin – rubber gloves. Works should not be carried out in patients' presence. After processing the premises, one should wash them and ventilate.

4.5. When carrying out works, one should observe the rules of personal hygiene. After work open body parts (face, hands) are to be washed with water and soap.

4.6. The detergent should be stored separately from pharmaceuticals, food products and out of children's reach.

5. First Aid

5.1. In case of violation safety measures while working with the detergent there can be irritation of upper respiratory passages, eyes and skin. If the symptoms of respiratory organs irritation occur, one should immediately stop working with the detergent, come out to the fresh air or to another room and the room is to be ventilated. The throat and the nasal cavity are to be washed with water. If necessary, seek medical assistance.

5.2. In case of direct contact with the skin, remove immediately the detergent from the skin with water and apply softening cream.

5.3. In case of direct contact with eyes, wash your eyes with large amounts of water for 10-15 minutes, drop in 30% solution of sulfacyl sodium and seek immediate medical assistance.

5.4. In case of taking the detergent in, one should drink several glasses of water, then take in 10-20 crushed absorbent carbon, then contact the doctor.

6. Physical –Chemical Methods of Detergent Control

6.1. The detergent is controlled in accordance with the parameters stated in Table 15:

Parameters	Norm
Appearance	Transparent liquid ranging from: colorless to yellow.
Mass concentration of basic nitrile and basic nitrile hydrochloride in conversion to basic nitrile, %	3.0 – 4.0
Mass concentration of alkyldimetilbenzylammonia chloride, %	11.0 – 13.0
Parameter of activity of hydrogen ions of water solution of the detergent with mass concentration of 2% at 20 °C, unit pH	5.6 – 8.0

6.2. Defining the appearance.

The state of appearance is defined visually by placing 50 cm³ of the analyzed product into a dry cylinder and watching it at the passing light.

6.3. Defining of mass concentration of basin nitrile and basic nitrile hydrochloride in conversion to basic nitrile.

Equipment, reagents, solutions

Ionometer or pHmeter of any brand with permissible deviation of no less than 0.05 units pH.

Electrodes: indicatory, glass, auxiliary – silver chloride (or calomel).

Magnet mixer

Laboratory scales of the forth class of accuracy.

Burette of the volume 10 cm³

Laboratory glassware

Cylinder of the volume of 50 cm³

Distilled water

Hydrochloric acid, solution of concentration with (HCl) = 0.5 mole/dm³

Sodium hydrate of concentration with (NaOH) = 0.5 mole/dm³

Isopropyl alcohol

Analysis carrying out

One should weight 10 –12 g of the tested product in the glass of 100 or 250 cm³ (results of weighing in grams are taken down up to the second decimal sign). 40 cm³ of isopropyl alcohol is added to the glass and carried out potentiometer titration of basic nitrile hydrochloride with the solution of sodium hydrate while mixing with magnet mixer. Then to the obtained solution one should add 1-2 ml of sodium hydrate solution, mix and carry out potentiometer titration with the solution of hydrochloric acid.

The curve of potentiometer titration with the solution of hydrochloric acid has two potential jumps: the first one corresponds to neutralization of the excessive amount of sodium hydrate, the second one - to neutralization of total amount of basic nitrile occurred as a result of titration of basic nitrile hydrochloride and the amine contained in the product test. Near the point of equilibrium the solution of the titrate is added in portions of 0.1 cm³, the volume of titrate of the corresponding point of equilibrium is calculated with the method of second derivative coefficient.

Results processing

Mass concentration of basic nitrile hydrochloride (X_1) in percentage in accordance with the formula:

$$X_1 = \frac{V_1 \cdot M_{\text{BNH}} \cdot 0,5 \cdot 100}{m \cdot 1000}, \text{ where}$$

V_1 is the volume of solution of sodium hydrate with exact concentration of 0.5 mole/dm³, spent on titration of basic nitrile hydrochloride, cm³

M_{BNH} is average molecular mass of basic nitrile hydrochloride calculated in accordance with the formula: $M_{\text{BN}} + M_{\text{HCl}}$, equal to $M_{\text{BN}} + 36.5$;

M_{BN} is molecular mass of basic nitrile (stated in the passport for the detergent);

m is the mass of the analyzed product, g.

Mass concentration of the basic nitrile and basic nitrile hydrochloride in conversion to basic nitrile (X_2) is calculated in percentage according to the formula:

$$X_2 = \frac{V_2 \cdot M_{\text{BN}} \cdot 0.5 \cdot 100}{m \cdot 1000}, \text{ where}$$

V_2 is the volume of solution of hydrochloric acid of exact concentration of 0.5 mole/dm³ spent on titration of the total amount of basic nitrile resulted from titration of basic nitrile hydrochloride with sodium hydrate and the amine contained in the product;

M_{BN} is molecular mass of basic nitrile (stated in the passport for the detergent);

m is the mass of the analyzed product, g..

For the result of the analysis one should take the average value of the results of two parallel definitions, absolute deviation between which does not exceed the permissible deviation, equal to 0.2 % in case confidence probability is $P=0.95$.

6.4. Measuring of mass concentration of alkyldimetilbenzylammonia chloride.

Equipment, glassware, reagents

Laboratory scales of general use of the 2nd class of accuracy

Measuring flasks of the following volumes 100, 200, 250, 500, 1000 cm³

Flask of KH. type of 100 cm³

Glass of 100 cm³

Cylinder of 10.25 cm³

Pipettes of 2, 5, 10 cm³

Burette of 5, 10 cm³ with scale interval of 0.02 cm³

Sodium chloride, chemically pure, of the solution with concentration of (NaCl)= 0.1 mole/dm³.

Silver nitrate, solution of concentration (AgNO₃) = 0.1 mole/dm³.

Ethanol

Isopropyl alcohol

Indicator: fluoresceine in accordance with the normative document, alcoholic solution of mass concentration 1 g/dm³ or fluoresceine - sodium (uranin) in accordance with the normative document, water solution of mass concentration of 1 g/dm³.

Distilled water

Preparation for analysis

Preparation of the solution of sodium chloride of concentration (NaCl)= 0.1 mole/ dm³.

0.5845 g of sodium chloride is weighed and transferred to the measuring flask of 100 cm³, then distilled water is added, weighing is dissolved and diluted up to the mark with distilled water and thoroughly mixed.

Preparation of the solution of silver nitrate with concentration of (AgNO₃) = 0.1 mole/dm³: 1.6987 g. of silver nitrate is weighed, transferred to the measuring flask of 100 cm³, then distilled water is added, and diluted up to the mark with water and thoroughly mixed.

The prepared solution is stored in dark glassware.

Fixing concentration of the solution of silver nitrate

2 (5) cm³ of the solution of sodium chloride is placed into the conic flask, then distilled water is added into the flask up to 20 cm³. 10 cm³ of isopropyl alcohol and 2-3 drops of indicator. The content of the flask is titrated with the solution of silver nitrate while intensive mixing. In the point of equilibrium there is the transfer of yellow-green coloration into rose-red. The average volume of the solution of silver nitrate (two titrations) spent on titration. The deviation between volumes of silver nitrate spent on titration should not exceed 0.04 cm³.

Concentration of the solution of silver nitrate C in mole/dm³, calculated according to the formula:

$$C = \frac{0,1 \cdot V_1}{V_2}, \text{ where:}$$

0.1 – concentration of the solution of sodium chloride, mole/dm³

V₁ – volume of the solution of sodium chloride taken for titration, cm³;

V₂ – volume of the solution of silver nitrate spent on titration, cm³.

Analysis carrying out

0.5000 ± 0.0200 g of the detergent is weighed in the conic flask, 20 cm³ of distilled water is added, then 10 cm³ of isopropyl alcohol and 2-3 drops of indicator are added and titrated with the solution of silver nitrate on intensive mixing till the transfer of coloration from green-yellow to rose-red.

Results processing.

Mass concentration of alkyldimetilbenzylammonia chloride X₃ in % is calculated according to the formula:

$$X_3 = \frac{V \cdot C \cdot M \cdot 100}{m \cdot 1000} - X_1 \cdot \frac{M}{M_{\text{BNH}}}, \text{ where:}$$

V is volume of the solution of silver nitrate spent on titration, cm³;

C is concentration of the solution of silver nitrate, mole/dm³;

M is average molecular mass of alkyldimetilbenzylammonia chloride (stated in the passport for the detergent),

m is the mass of the detergent weighing, g;

X₁ is the mass concentration of basic nitrile chloride (p.6.3), %,

For the result of analysis one should take an average value of two parallel measurements, absolute deviation between which should not exceed 0.2% in case confidence probability is P = 0.95.

Permissible absolute total deviation of the measuring results is ± 0.4% in case confidence probability is P = 0.95.

6.5. Measuring the parameter of the hydrogen ions activity

Measuring the parameter of the hydrogen ions activity, pH of water solution of the detergent with mass concentration of 2% is carried out in accordance with the State Standard P 50550.-93 with potentiometer method.

7. Transportation and Storage Conditions

7.1. The detergent is transported by railway and automobile transport in covered vehicles in accordance with the rules of goods transportation valid for the corresponding means of transport.

7.2. The detergent is stored in the producer's package at the temperature not higher than plus 40°C far from the sources of light. It is possible to transport the detergent at the temperature ranging from minus 30°C to plus 40°C. In case of detergent freezing it should be kept at the temperature of plus 20-40°C till occurrence of homogeneous transparent solution. After it is thawed, the detergent preserves its activity and does not lose its qualities.

7.3. In the event a large amount of the detergent is poured out, it should be diluted with large amounts of water or be absorbed with noninflammable substances (sand, rasping, waste cloth, silica gel), be collected into containers and sent to utilization. Cleaning of the poured detergent should be carried out in special uniform: rubber apron, rubber boots and personal protection equipment for hand skin (rubber gloves), eyes (protection glasses), respiratory organs (multifunctional respirators of the type PY 60 M, ППГ-67 with the plug of B type).

Pouring the detergent into the collecting system is permissible only if it is diluted.