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TO: Chief Executive Officer of OOO MKM STROY
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In response to your inquiry w/o No. dated 27.03.2020
about the use of disinfecting agent SABISEPT M
by PFNI GORMOST
for motor-road objects (bridges, under-bridge spaces,
tunnels, sidewalks), we provide
the description of the agent and instructions for use.

INSTRUCTION No. 07/20

for use of the disinfecting agent
SABISEPT M

for disinfection of elements of automobile roads, tunnels, pedestrian crossings, bridges,
under-bridge spaces

Sabisept M has a number of advantages in comparison with many foreign and Russian disinfectants. The virucidal activity of Sabisept M indicates its disinfecting activity against all known human pathogens, including enteral and parenteral hepatitis viruses, HIV, poliomyelitis, adenoviruses, SARS viruses ("atypical pneumonia"), human influenza and "bird flu" H5N1, herpes viruses, etc.

Sabisept M does not contain hazardous components (*active chlorine, aldehydes, phenols*), working solutions are safe for direct contact and do not have an inhalation effect, which allows you to work without respiratory protection, in the presence of people.

The agent is widely used for surface disinfection of sanitary equipment, rigid furniture, the exterior of devices and apparatuses; linen, dishware, patient care items, cleaning equipment, rubber mats, medical waste in case of viral and bacterial infections. The agent eliminates fungal formations during disinfection in medical institutions, including: medical disinfection in case of bacterial infections (including tuberculosis – the agent is tested for activity against the M.Terrae strain), viral infections, candidiasis and dermatophytes, precleaning before sterilization, as well as cleaning combined with disinfection of medical devices (including dental instruments, flexible and rigid endoscopes), in affected areas, disinfection of medical transport, public utilities (hotels, dormitories, hairdressers, laundries, public toilets), institutions of education, culture, recreation, sports and social services, children's and detention institutions, as well as disinfection of objects of railway transport and subway.

The agent was clinically tested by the N. N. Burdenko Main Military Clinical Hospital of the Ministry of Defense of the Russian Federation. According to the results of this testing, given the wide range of antimicrobial action and additional properties of this

disinfectant, it was recommended for use as part of preventive (anti-epidemic) measures at times of war and local military conflicts.

Sabisept M was also clinically tested by Federal State Institution "Center of State Sanitary and Epidemiological Surveillance" of the Administrative Department of the President of the Russian Federation, by Federal Service for the Execution of Sanctions of the Ministry of Justice of the Russian Federation, Federal State Unitary Enterprise "Russian National Research and Development Institute of Railway Hygiene of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing", Federal State Healthcare Institution "Hygienic and Epidemiological Center in Moscow" and was recommended for use.

This instruction is applicable to the SABISEPT M disinfecting agent, (OOO NPF Sabina-Grand, Russia), according to TU 9392-001-74518126 2005.

1. Scope of application.

SABISEPT M disinfecting agent is allowed for use in preventive, routine and final disinfection of rooms, pieces of furniture, sanitary equipment on any elements of automobile roads, tunnels, pedestrian crossings, bridges, under-bridge spaces of Russia, including roadbed, sidewalks, load-bearing structures, finishing structures, amenities and other facilities under hierarchical powers.

Preventive disinfection of elements of automobile roads, tunnels, pedestrian crossings, bridges, under-bridge spaces, carried out by washing teams, means sanitary cleaning of the element with disinfecting agents by applying or wiping surfaces.

2. Contents and properties of SABISEPT M disinfecting agent.

2.1 SABISEPT M disinfecting agent is a transparent liquid from colorless to yellow. Sabisept M disinfecting agent consists of 12% of alkyldimethylbenzylammonium chloride (quaternary ammonium salt) and 3.5% of tertiary amine as active ingredients. The agent also contains neonol and other components. The agent is easily mixed with water. The 2% water solution of the agent has pH of 5.6-8.0 and has detergency properties. The warranted shelf life of the agent is 5 years if stored in unopened package, the shelf life of the working solutions is 14 days if stored in closed containers. A small amount of sediment is allowed to fall out during long-term storage. The agent does not lose its performance upon freezing and subsequent thawing.

2.2. SABISEPT M has antimicrobial activity against gram-negative and gram-positive bacteria (including *Mycobacterium tuberculosis*), viruses (any known human pathogenic viruses, including enteral and parenteral hepatitis virus, HIV, poliomyelitis, adenoviruses, "atypical pneumonia", herpes and "bird flu" viruses), fungi of the *Candida*, *Trichophyton*, *Aspergillus* genera.

The agent does not lose its performance upon freezing and subsequent thawing.

2.3. According to GOST 12.1.007-76, Sabisept M pertains to class 3 of moderately hazardous substances when administrated into the stomach, and to class 4 of low-hazard substances when applied to the skin and administrated parenterally. The agent in its native form has an irritation effect in case of contact with skin and mucous membranes of the eyes, and has a weak sensitizing effect. The thresholds of irritation effect on the mucous membranes of the eyes and on the skin are 1.0% and 2.0% respectively. At saturating concentrations, single inhalation exposure to the vapors of the agent (solutions with a concentration of 10% and lower), belonging to the 4th class of low-hazard substances, presents a low hazard.

MAC in the air of the working area for alkyldimethylbenzylammonium chloride is 1 mg/m³.

MAC in the air of the working area for tertiary amine is 2 mg/m³.

2.4. SABISEPT M does not make a negative impact on the surfaces made of colored decorative plastic (paper-based laminate, fiberglass), stamped surfaces of low-combustible vinyl artificial leather, marble, wooden surfaces (treated with fire-retarding and preservative agents), rubber for handrails, pile polyether fire-retardant fabric and other surfaces of objects.

2.5. For preventive disinfection, it is recommended to use a polymer container with a capacity of 1 dm³ to 5.0 dm³. For the preparation of working concentrations at the rate of 5 ml per 10 liters of water in accordance with Table 1, the polymer container should go with a measuring container 1

3. Preparing the working solutions of SABISEPT M disinfecting agent.

3.1. Working solutions of the disinfecting agent for the elements of automobile roads, tunnels, pedestrian crossings, bridges, under-bridge spaces should be prepared by sanitary service in servicing points or other stationary facilities in separate rooms only. To make a working solution, add the exact amount of concentrate (a measuring container should be provided) to the measured amount of drinking water at room temperature in accordance with the calculations given in Table 1. The prepared working solutions should be stored in polymer containers only.

Table 1.

Preparing the working solutions of SABISEPT M disinfecting agent

Solution concentration (%) per:			The amount of the agent (ml) required for preparing:			
Agent	Active ingredients		1 liter of working solution		10 liters of working solution	
	Quaternary ammonium salt	Amine	Agent (ml)	Water (ml)	Agent (ml)	Water (ml)
1.0	0.12	0.03	10.0	990.0	10.0	9900.0
2.0	0.24	0.07	20.0	980.0	200.0	9800.0

4. Using the SABISEPT M disinfecting agent for preventive disinfection.

Preventive disinfection of elements of automobile roads, tunnels, pedestrian crossings, bridges, under-bridge spaces is performed with working solutions of the agent by applying or wiping.

4.2. For preventive disinfection of walls and surfaces of rooms within facilities, use 1.0% solutions (per agent) of the SABISEPT M disinfecting agent at the rate of 150 ml per 1 m² of the treated surface. Exposure time is 60 minutes. For disinfection of sanitary equipment, trash bins, use 1.0% solutions of the SABISEPT M after double wiping with an

interval of 15 minutes between treatments and a total exposure time of 60 minutes. The consumption rate for double treatment is 300 ml per 1 m². Wet cleaning on the elements of automobile roads, tunnels, pedestrian crossings, bridges, under-bridge spaces is not required after disinfection with SABISEPT M (i.e. the disinfectant does not need to be washed off from the treated surfaces). If you find down-flows on the treated surfaces after exposure, wipe them with dry disinfected cleaning equipment.

4.3. Schemes of preventive disinfection of elements of automobile roads, tunnels, pedestrian crossings, bridges, under-bridge spaces are shown in Table 2. The disinfection scheme for cleaning equipment is taken from the instruction No.1 for use of SABISEPT M in hospitals, developed by Federal State-Funded Institution of Science "Research and Development Centre of Disinfectology" of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing.

Table 2. Schemes of preventive disinfection of elements of automobile roads, tunnels, pedestrian crossings, bridges, under-bridge spaces with SABISEPT M

Decontaminated element	Concentration of the working solution per agent %	Decontamination time, min. (exposure)	Method of decontamination
<u>Tunnels of automobile roads</u> (walls, niches, surfaces of windows and doors, external and internal surfaces of trunks, handles, handrails, floors).	1.0	60	Single wiping
<u>Pedestrian crosswalks</u> (walls, niches, floors, surfaces of windows and doors, external and internal surfaces of trunks, handles, handrails, floors).	1.0	60	Single wiping
<u>Road bridges</u> (asphalt surfaces, edges, load-bearing structures).	1.0	60	Single wiping
<u>Objects of constant contact</u> (doors of underground passages, handles, glasses, seats, benches, handrails, etc.).	2.0	60	Double wiping with an interval of 2-3 min.
<u>Departmental stationary facilities</u> (restrooms for the crews, dispensaries, and other rooms).	1.0	60	Single wiping
<u>Cleaning equipment.</u>	2.0	60	Soaking
<u>Toilets</u> (sanitary equipment, walls, floor). Trash bins, boxes for garbage collection.	1.0	60	Double wiping with an interval of 15 minutes

4.4. Pedestrian crossings, objects of constant contact, stationary elements. Disinfection is performed by wiping in accordance with the schemes given in Table No.2 as per the following schedule:

- walls – 1 time per week;
- objects of constant contact – 2 times a week;
- sanitary equipment and toilet rooms – 1 time per day;
- restrooms, dispensaries – 1 time per day.

In the event of an unfavorable epidemiological situation, preventive disinfection of all facilities with SABISEPT M should be performed daily – at least once a day. Mother-and-child room – 3 times a day. Toilet rooms and sanitary equipment – at least 3 times a day. The walls of the rooms in the toilets should be treated to a height of at least 1.5 meters from the floor. Cleaning equipment should be treated with particular care.

4.5. Tunnels, bridges. For preventive disinfection, it is recommended to use the working solutions of SABISEPT M (see Table 2). Preventive disinfection should be performed daily by cleaning crews.

5. Using SABISEPT M for the disinfection (routine and final) of affected areas.

SABISEPT M disinfecting agent may be used in case of epidemiological indications for routine disinfection in the presence of a patient with confirmed or suspected infectious disease, and for final disinfection (after a patient with confirmed or suspected infectious disease leaves the room).

In case of epidemiological indications, routine and final disinfection is performed by the institutions providing disinfection services (Department of Prophylactic Disinfection) by spraying. They should use the schemes described in "Instructions No.1 for use of SABISEPT M disinfecting agent (OOO NPF Sabina Grand, Russia) at health care facilities and affected areas", designed by Federal State-Funded Institution of Science "Research and Development Centre of Disinfectology" of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing.

6. Precautions

6.1. During preparing and using of working solutions, wear rubber gloves to protect hand skin.

6.2. Avoid contact of the concentrate and working solutions with eyes and skin.

6.3. Preventive disinfection of passenger-carrying constructions should be performed by wiping the surfaces of the room and can be done in the presence of people.

6.4. When using the solutions of the agent for soaking, the containers must be closed with lids.

6.5. When using the agent, follow the rules of personal hygiene . Do not smoke, drink or eat. After work, wash your face and hands with soap and water.

6.6. The agent should be stored in closed containers separately from food and medicines, out of the reach of children.

7. First aid measures in case of accidental poisoning

7.1. In case of accidental contact with eyes, rinse them thoroughly with water for 10-15 minutes, then put 1-2 drops of 30% solution of sodium sulfacyl.

7.2. in case of contact with skin, wash it off with soap and water.

7.3. In case of accidental ingestion of the agent, drink several glasses of water with powdered tablets of activated carbon (10-20 pcs.). Do not induce vomiting!

7.4. Seek medical advice when necessary.

8. Shipping, storage

8.1. The agent should be shipped by road in covered vehicles in accordance with the rules of cargo transportation applicable to this type of transport.

8.2. The agent should be stored in the original package in warehouse premises at a temperature not exceeding plus 40°C, away from sources of light. The agent can be stored in open sheltered areas. The agent can be shipped at a temperature of minus 30°C to plus 40°C. If the agent is frozen, leave it at a temperature of plus 20-40°C until a homogeneous transparent solution is formed. The agent retains its activity and consumer properties after thawing.

8.3. In the event of a spill, dilute it with a large amount of water or adsorb with non-flammable substances (sand, sawdust, rags, silica gel), collect in containers, and send for disposal. Use special clothes when cleaning the spilled agent: rubber apron, rubber boots and personal protective equipment for the skin of hands (rubber gloves), eyes (safety glasses), respiratory organs (universal respirators of the type RU 60 M, RPG-67 with a cartridge B).

Drain the agent into sewer systems in a diluted form only.

9. PHYSICAL, CHEMICAL AND ANALYTICAL QUALITY CONTROL METHODS OF SABISEPT M DISINFECTING AGENT

9. Physical and chemical quality control methods

9.1. The agent quality is controlled according to the parameters given in Table 3:

Table 3 - Physical and chemical parameters for quality control of the agent.

Name of parameter	Normal range
Appearance	Transparent liquid: from colorless to yellow
Weight content of tertiary amine and tertiary amine hydrochloride expressed as tertiary amine, %	3.0-4.0
Weight content of alkyldimethylbenzylammonium chloride, %	11.0-13.0
Exponent of hydrogen ion activity in 2% w/w water solution of the agent at the temperature of 20°C, pH of	5.6-8.0

9.1. Appearance assessment

The appearance of the agent is assessed visually by placing 50cm³ of the analyzed product in a clean dry cylinder and viewing it in transmitted light.

9.1. Determining the weight content of tertiary amine and tertiary amine hydrochloride expressed as tertiary amine.

Equipment, reagents, solutions.

Ionometer or pH-meter of any manufacturer with the uncertainty of measurement of not more than 0.05 of pH unit.

Electrodes: indicating, glass, auxiliary – silver-chloride or kalomel.

Magnetic stirrer.

Laboratory scales (4th class of accuracy).

Burette with a capacity of 10cm³.

Laboratory glassware.

Cylinder with a capacity of 50cm³.

Distilled water.

Hydrochloric acid, a solution with the concentration $c(\text{HCl}) = 0.5 \text{ mol/dm}^3$

Sodium hydroxide, a solution with the concentration $c(\text{NaOH}) = 0.5 \text{ mol/dm}^3$

Isopropyl alcohol.

Conducting an analysis.

Weigh 10-12 g of the analyzed product in a glass with a capacity of 100 or 250 cm³ (the results of weighing are recorded in grams to two decimal places). Add 40 cm³ of isopropyl alcohol to the glass, mix and carry out a potentiometric titration of tertiary amine hydrochloride with a solution of sodium hydroxide by stirring with a magnetic stirrer. Then add 1-2 ml of sodium hydroxide solution to the resulting solution, mix and carry out a potentiometric titration with a solution of hydrochloric acid the same way.

The curve of potentiometric titration with hydrochloric acid solution has two potential jumps: the first one corresponds to the neutralization of an excess amount of sodium hydroxide, the second one corresponds to the neutralization of the total amount of tertiary amine resulted from titration of tertiary amine hydrochloride and amine contained in the product sample. Close to the equivalence point add the titrant solution in portions of 0.1 cm³, the volume of the titrant solution corresponding to the equivalence point is determined by calculation: by the second derivative method.

Processing the results.

The weight content of tertiary amine hydrochloride (X_1) as a percentage is calculated by the formula:

$$X_1 = \frac{V_1 \cdot W_{\text{TAH}} \cdot 0.5 \cdot 100}{m \cdot 1000}, \text{ where}$$

V_1 is the volume of sodium hydroxide solution with an exact concentration of 0.5 mol/dm³ used for titration of tertiary amine hydrochloride, cm³;

M_{TAH} is the average molecular weight of tertiary amine hydrochloride calculated by the formula: $M_{\text{ta}} + M_{\text{ncl}}$, equal to $M_{\text{ta}} + 36.5$;

M_{ta} is the molecular weight of the tertiary amine (indicated in the certificate of the agent);

m is the weight of the analyzed product, g.

The weight content of tertiary amine and tertiary amine hydrochloride expressed as tertiary amine (X_2) as a percentage is calculated by the formula

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

V_2 is the volume of a hydrochloric acid solution of an exact concentration of 0.5 mol/dm³ used for titration of the total amount of tertiary amine resulted from titration of tertiary amine hydrochloride with sodium hydroxide and the amine contained in the product;

M_{ta} is the molecular weight of the tertiary amine (indicated in the certificate of the agent);

m is the weight of the analyzed product, g.

The result of the analysis is the arithmetic mean of the results of two parallel determinations with absolute divergence between them not exceeding the allowable divergence of 0.2% with a confidence interval of $P=0.95$.

8.4. Measurement of the weight content of alkyldimethylbenzylammonium chloride.

Equipment, utensils, reagents.

General purpose laboratory scales (2nd class of precision).

Measuring flasks with a capacity of 100, 200, 250, 500, 1000 cm³.

Flask (type Kn.) with a capacity of 100 cm³.

Glass with a capacity of 100 cm³.

Cylinder with a capacity of 10.25 cm³.

Pipettes with a capacity of 2, 5, 10 cm³.

Burette with a capacity of 5, 10 cm³ with a division value of 0.02 cm³.

Sodium chloride, chemically pure, solution with the concentration $c(\text{NaCl}) = 0.1$ mol/dm³.

Silver nitrate, a solution with the concentration $c(\text{AgNO}_3) = 0.1$ mol/dm³.

Ethyl alcohol.

Isopropyl alcohol.

Indicator: fluorescein (resercinphthalein) according to the regulatory document, alcohol solution with a mass concentration of 1 g/dm³ or fluorescein-sodium (uranin) according to the regulatory document, aqueous solution with a mass concentration of 1 g/dm³.

Distilled water.

Preparation for analysis.

Prepare sodium chloride solution with the concentration $c(\text{NaCl}) = 0.1$ mol/dm³.

Weigh 0.5845 g of sodium chloride, transfer quantitatively to a measuring flask with a capacity of 100 cm³, add distilled water, dissolve the suspension, dilute to volume with distilled water and mix thoroughly.

Prepare a solution of silver nitrate with the concentration $c(\text{AgNO}_3) = 0.1$ mol/dm³: Weigh 1.6987 g of silver nitrate, transfer quantitatively to a measuring flask with a capacity of 100 cm³, add distilled water, dissolve, dilute the volume with water and mix thoroughly.

Store the prepared solution in a dark glass container.

Determination of the concentration of silver nitrate solution.

Place 2 (5) cm³ of sodium chloride solution into a conical flask, add distilled water up to 20 cm³ to the flask. 10 cm³ of isopropyl alcohol and 2-3 drops of the indicator. Titrate the contents of the flask with a solution of silver nitrate applying intensive stirring. The color of the solution changes from yellow and green to pink and red at the equivalence point. Calculate the average volume of silver nitrate solution (two titrations) used for titration. The

divergence between the volumes of the silver nitrate solution used for titration should not exceed 0.04 cm³.

The concentration of silver nitrate solution c in mol/dm³ is calculated by the formula:

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

0.1 is the concentration of sodium chloride solution, mol/dm³.

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

V₂ is the volume of silver nitrate solution used for titration, cm³.

Conducting an analysis

Weigh 0.5000 ± 0.0200 g of the agent in a conical flask, add 20 cm³ of distilled water, 10 cm³ of isopropyl alcohol, 2-3 drops of the indicator and titrate with a solution of silver nitrate applying intensive stirring until the color of the solution change from yellow and green to pink and red.

Processing the results.

The weight content of alkyldimethylbenzylammonium chloride X₃ in % is calculated by the formula:

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

V is the volume of silver nitrate solution used for titration, cm³.

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

M is the average molecular weight of alkyldimethylbenzylammonium chloride (indicated in the certificate of the agent),

m is the sample weight of the agent, g;

X₁ is the weight content of tertiary amine hydrochloride (sec. 6.3), %,

The result of the analysis is the arithmetic mean of the results of two parallel determinations with absolute divergence between them not exceeding the allowable divergence of 0.2% with a confidence interval of P=0.95.

The allowable absolute cumulative error of the measurement is ± 0.4% with a confidence interval of P=0.95.

9.2. Determination of the exponent of hydrogen ion activity

Measurement of the exponent of hydrogen ion activity, pH of an aqueous solution of the agent with a weight content of 2% w/w is conducted using the potentiometric method according to GOST R 50550.-93.

Chief Executive Officer _____ S.N. Abros'kin

03/27/2020

