

MINISTER OF HEALTH OF THE REPUBLIC OF ARMENIA

ORDER

September 28, 2023, Order No. 4638-A

Approval of instructions for the use of "Me-Ga" PLUS disinfectant

Based on the decision No. 728-L of June 11, 2018, by the Prime Minister of the Republic of Armenia, and in accordance with sub-clause 20 of Charter 18 of the Republic of Armenia's Health Minister, as well as Appendix 19 of Order No. 48 dated September 10, 2015.

I ORDERED

1. Approve the "Me-Ga" PLUS disinfectant instructions as per Appendix A
2. Lilit Babakhanyan, Head of Public Relations at the Ministry of Health, has placed the order in the Health Department on the official website of the Ministry.
3. This order shall come into effect on the day following its publication.

Armenian Minister of Health
A. Avanesyan

СОГЛАСОВАНО

Руководитель ИЛЦ
ФБУН ГНЦ ПМБ



« 25 » июля

/Храмов М.В.

2023г.



УТВЕРЖДАЮ

Генеральный директор

ЗАО «ПАПИКЯН

ЗДРАВООХРАНИТЕЛЬНАЯ

ПРОДУКЦИЯ»



/Т.С.ПАПИКЯН

« 25 » июля

2023г.

Инструкция № 2/23
по применению средства дезинфицирующего в виде пены
«Me-Ga Plus»

Москва 2023

AGREED
Head of ILC
FBUN SSC PMB

COFIRMED
CEO
"PAPIKYAN HEALTH CARE PRODUCTS" CJSC

Khramov M.V.
"25" July 2023

T.S. PAPIKYAN
"25" July 2023

INSTRUCTIONS No. 2/23

for the use of disinfectant in the form of foam "Me-Ga Plus"

Moscow, 2023

INSTRUCTIONS No. 2/23

for the use of disinfectant in the form of foam "Me-Ga Plus"

The instructions were developed by the Federal Budgetary Institution of Science "State Scientific Center for Applied Microbiology and Biotechnology" (FBUN "SSC Applied Microbiology and Biotechnology"); RF; CJSC "PAPIKYAN HEALTH PRODUCTS", RA.

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(FBUN "SSC Applied Microbiology and Biotechnology");

Kazaryan A. (PAPIKYAN HEALTH PRODUCTS CJSC).

1. GENERAL PROVISIONS

1.1. "ME-GA" PLUS FOAM disinfectant (hereinafter referred to as the product) is a clear liquid with an alcohol scent. The active substances include ethyl alcohol ($56.0 \pm 0.2\%$), propyl alcohol (22%), chlorhexidine bigluconate, and functional additives, such as skin care ingredients. The formulation also includes water, with a product pH ranging from 5 to 8 units, and a product density of $0.80-1.0 \text{ g/cm}^3$.

The product has a shelf life of 5 years from the date of issue when stored in the manufacturer's tightly closed package in a dry place, within the temperature range of $+5^\circ\text{C}$ to $+30^\circ\text{C}$.

Packaging for the product is done in polymer bottles with capacities ranging from 0.05 L to 1 L.

1.2. The product exhibits antimicrobial activity against both gram-negative and gram-positive bacteria, including *Mycobacterium tuberculosis* (tested on *Mycobacterium terrae*) and nosocomial infection pathogens (tested on *Pseudomonas aeruginosa*, enteric bacteria such as spp., staphylococci, salmonella). It also demonstrates efficacy against legionellosis and special products of dangerous infections such as plague, cholera, and tularemia. Additionally, it shows antiviral activity against a range of viruses, including rhinoviruses, noroviruses, rotaviruses, adenoviruses, intra-abdominal and extra-abdominal hepatitis viruses (including A, B, C, D), polio viruses, Coxsackie enteroviruses, ECHO, HIV, influenza viruses (including 'swine' H1N1 and 'bird' H5N1), parainfluenza, coronaviruses, 'atypical pneumonia' pathogens (SARS, MERS), herpes, measles, acute respiratory viral infections, cytomegalovirus infection, and demonstrates fungicidal activity against fungi of the genus *Candida* and *Trichophyton*.

The product exhibits an extended antimicrobial effect lasting for 3 hours.

No washing is required after treatment with the product.

1.3. In terms of acute toxicity criteria, as per GOST 12.1.007-76, the product is classified as less dangerous, falling into the 4th grade for both ingestion and skin contact. Importantly, it is also categorized as less toxic in the 4th class according to K. K. Sidorov classification when ingested. The product shows local irritant properties, with minimal skin resorptive and sensitizing effects under recommended usage conditions. Cumulative effects are absent. The product has a moderate irritating effect on the eyes and mucous membranes. When used according to recommended application regimens, the inhalation hazard falls into the little danger category in the 4th class of hazardous substances.

- The Maximum Allowable Concentration (MAC) for ethyl alcohol in the air of the working zone is 1000 mg/m³ (vapors, danger class 4).

1.4. The disinfectant is used

- in healthcare facilities, including organizations providing medical care and service (hereinafter medical organization), including ambulatory polyclinic and inpatient medical organizations, sanatoriums, rehabilitation centers, multidisciplinary medical centers, medical centers and medical centers, medical and midwifery centers, maternity inpatients, neonatal wards, neonatal centers and departments, children's departments, dental clinics and departments, endoscopy and colonoscopy departments, medical offices and medical centers of various institutions, diagnostic cabinets, intensive care and resuscitation, trauma departments, burn centers, centers for organ transplantation, blood transfusion and collection stations, an-tuberculosis (or phthisiatric) institutions, dermatological and venereological dispensaries, mycological and other, of all kinds in sanitary transport, including an ambulance in transport conditions, in disinfection-oriented institutions, including sanatoriums, in laboratories (including microbiological, virological, mycological, immunological, clinical, diagnostic and etc.), in pharmacies and pharmacy institutions, emergency situations and in the area of natural disasters, centers of infection, organizations and in departments: Ministry of Internal Affairs (MIA) Police and Rescue Service, Civil Defense Forces (CP) and formation in personnel, water supply and power grid facilities, military in departments, penitentiaries, etc., perfumery-cosmetics, chemical-pharmaceutical, biotechnological and in institutions of microbiological industry, veterinary in facilities, poultry, animal breeding, animal breeding farms, food industry organizations (meat, milk, poultry processing, baking, confectionery, etc.), public food, industrial markets, trade organizations, children's in pre-school and school institutions, administrative facilities, social security services (elderly, home for the disabled, hospice, etc.), education, culture, recreation, sports in institutions and organizations, health resort in institutions, in all types of transport, including food and transportation of food raw materials, service industry in facilities (including hotels, hostels, public toilets, beauty salons, hairdressing and cosmetology salons, solariums, baths, saunas and other health facilities entertainment complexes), in shopping and entertainment centers, in industrial markets, retail trade organizations, in facilities of ritual services, morgues, etc.

The disinfectant is intended for the following:

- For hygienic processing of hands - medical organizations medical personnel, sanitary transport, urgent and urgent medical aid stations, laboratories (including microbiological, mycological, virological, immunological, clinical, criminological and others) employees, donation points, blood transfusion points, employees of medical and sanitary departments, pharmacies and pharmacies employees of organizations, perfumery-cosmetics, pharmaceutical, biotechnological and microbiological employees of industrial establishments, emergency situations zones, penitentiary institutions, service

sector in facilities (including beauty salons, hairdressing and cosmetology salons, spa-salons, bathroom-laundry complexes, hotel facilities, etc.), ceremonial service facilities, morgues, public transport facilities, public food, milk kitchen, markets, food and poultry, livestock, swine and livestock in enterprises of the processing industry of farms, in commercial organizations (including cashiers and securities other working persons) for hygienic treatment of employees' hands,

- surgeons and surgical in medical organizations for handling the hands of other persons participating in interventions (including in dental organizations, as well as in maternity hospitals – birth when receiving, etc.)
- for processing the injection field of patients, including during vaccinations,
- In a medical organization, blood transfusion and collection stations for the processing of donor arm folds,
- for treatment of the surgical field, including joints and organs during catheterization and puncture (including therapeutic and diagnostic punctures, catheterization of peripheral and central vessels, spinal punctures, epidural space catheterization, joints puncture), piercing, cutting, biopsy when performing medical in organizations, various institutions, social of security institutions (home for the elderly, disabled, etc.) in medical offices, sanatorium-resort facilities, in penitentiary and other institutions, as well as emergency services in conditions of transport by vehicles and emergency situations time,
- for partial sanitizations of the skin, including lying down (bed) patients,
- for treatment of feet: bath, shower, sauna, prevention of fungal diseases after visiting the pool for the purpose of prevention and neutralization of emergency situations representatives of departments, rescuers of the Ministry of Internal Affairs, personnel of civil defense troops and formation, penal foot preventive for those in institutions, adults for processing,
- gloves worn on the hands of the medical staff (from chloroprene rubber, latex, neoprene, nitrile and other chemical resistant materials) for disinfection, including pouring an infectious product onto the glove case, during the collection of medical waste, as well as sterile employees of production establishments,

It is used as a disinfectant for various purposes:

- Quick disinfection of alcohol-resistant surfaces in medical organizations, including dental offices, reception departments, resuscitation, surgical, ophthalmological, children's hospitals, maternity hospitals, obstetric clinics (including neonatology departments, neonatal rooms, IVF departments), bandages, outpatient examination rooms, blood transfusion stations, centers of infection, isolation rooms, diagnostic, clinical, microbiological, and other laboratories, vehicles of ambulance services, Civil Defense Forces, Ministry of Internal Affairs, sanitary transport, children's preschools, schools, penitentiary institutions, chemical pharmaceutical and biotechnology industries, public food, shopping facilities, food and processing industry institutions, veterinary organizations, service facilities (barber shops, massage and cosmetics salons, beauty salons, spa-salons, hotels, hostels, social service providers, laundries, morgues, etc.), and facilities of regional health significance (swimming pools, bathhouses, saunas, etc.) for quick disinfection.
- disinfection of hard-to-reach surfaces,
- furniture accessories (including surgical, germicidal lamps, and other lighting devices), hard and so goods (including surgical interventions, diapering, birth, operations, operating tables,

gynecological and dental chairs, resuscitation mattresses, mattresses with casings in departments, etc.), stretchers, wheelchairs, headrests, elbow rests, handles, door and window handles, fan grilles, etc., sanitary-technical equipment, sports equipment, and personal hygiene means.

- disinfection of surfaces of devices and equipment, including medical equipment control panels, artificial lungs outside of ventilator, anesthesia and hemodialysis devices, surfaces, non-removable parts and joints of endoscopic devices, external surfaces of medical thermometers, optical devices allowed by the manufacturer to process alcohol-based disinfectants.
- in outbreaks of infectious diseases, including plague, cholera, tularemia, coronavirus, small surfaces in furniture, hard goods, disinfection of devices and equipment.
- disinfection of diagnostic equipment (USR and others) and other similar medical disinfection of surface (skin) sensors of products that allow disinfection by contact.
- in clinical, microbiological, virological, and other laboratories, surfaces of laboratory property and equipment, including objects for disinfection of glasses (immersion oil cleaning).
- disinfection of patient care items, non-porous toys, flat surfaces (plastic, glass, metal, etc.) for disinfection,
 - in ambulances and sanitary transport for disinfection of equipment and surfaces,
 - disinfection of physiotherapy equipment,
 - disinfection of cardio electrodes (clamp, p, clip, chest electrodes).
 - disinfection of various materials (metal, glass, plastic, rubber) medical products of significance (except surgical, and those with cavities and tubes) for disinfection, including medical thermometers, X-ray cassettes, tonometer arms, stethoscopes, phonendoscopes and photophonendoscopes, dental instruments (except rotary), dental handpieces.
 - in the morgue and pathology service building, small surfaces of forensic examination facilities, columbariums, funeral homes, office-stores, mourning ceremony halls, buildings of other organizations providing funeral services, as well as hearses.
 - disinfection in small rooms of the pharmaceutical and biotechnological industries and equipment and non-sterile drug production class C and D purity.
 - in solariums, special hairdressers, stable surfaces, manicure and pedicure tools, and disinfection of device terminals that are not susceptible to sterilization in hairdressers, beauty salons, cosmetology salons, and others in the service sector in organizations that demonstrate hairdressing and cosmetology services.
 - for disinfection of rubber and polypropylene carpets, wax diapers.
 - for disinfection of the inner surfaces of shoes (rubber and plastic) to prevent fungal diseases and eliminate unpleasant odors.
 - monitors (except for liquid crystal displays), computer accessories (keyboard, microphone, printer, etc.), telephones (mobile telephone, copier, and other office equipment) for disinfection, s. banknote and coin counters, foreign exchange and excise stamp detectors, document destruction devices, vault for disinfecting cabinets and shelves,
 - air conditioning and ventilation system (domestic air conditioners, split system, multi-zonal split-system, roof air conditioners, air ducts, ventilation filters, etc.) for disinfection,
 - for household use by the population, apply to not large furniture surfaces and hard-to-reach surfaces to clean and disinfect household items (for adults and children over the age of 10).
 - hand hygiene for adults and children over 10 years old for processing.

2. APPLICATION OF THE DISINFECTANT FOR HAND HYGIENE

2.1. Hygienic processing of hands: On dry wrists (without water and pre-washing with soap), pour 3 ml of the product. Massage the product into the skin until dry, for at least 30 seconds, paying attention to the inter-finger areas, fingertips, and the skin surrounding the nail.

For tuberculosis prevention, pour the product into the palms of the hands twice, using at least 3 ml each me. The total processing time should be at least 2 minutes to prevent viral infections.

2.2. Treatment of hands for surgeons and other individuals involved in surgery: Prior to applying the product, thoroughly wash wrists and forearms for 2 minutes with warm running water and soap. Dry the washed areas with a sterile tanzive tissue. Apply the product in portions (2-3 ml) to dry hands twice, ensuring the skin remains moist during the treatment. Massage each portion into the skin of the wrists and forearms for 2.5 minutes until completely dry. The total processing time is 5 minutes. Wear a sterile glove over dry hands, completing the process after drying.

The product exhibits an extended antimicrobial (residual) effect for 3 hours.

2.3. Processing of the surgical field and the donor axillary fold, including before catheter placement: Rub the skin twice with separate sterile tanzive pulps, abundantly soaked. Post-processing period: 2 minutes.

2.4. Development of the injection field, including the vaccination site:

- Rub the skin (in one direction) with a richly moistened sterile cotton wool. Allow a timeout of at least 20 seconds after completion of processing.
- Spray the product on the injection site until completely wet. Allow a further delay after processing for at least 20 seconds (until the product is completely dry).

2.5. Processing of welded glass ampoules (vials) before injection: Rub the upper third of the welded ampoule through abundantly moistened sterile broth. Allow timeout of at least 20 seconds after processing.

2.6. Preventive treatment of feet (swimming pool, sauna, shower, and after attending other places): Thoroughly rub each foot with a separate cotton pad, abundantly moistened. Process each foot for at least 1 minute with different fillings. For the prevention of fungal infections, the disinfection period is 3 minutes.

2.7. Latex, neoprene, nitrile (and other materials) gloves and product development: For surface disinfection of the glove, pour 2.5 ml of the product into the gloved palm. Rub the surface of the gloves on both hands for 15 seconds, making hand movements to ensure thorough coverage. Alternately, process through abundantly moistened sterile cotton or tanzive curd. Total processing me: 30 seconds. Disinfectant period: at least one minute for bacterial (except tuberculosis) infections, and at least 5 minutes for bacterial (including tuberculosis), viral, and fungal infections.

During contamination of gloves with products, blood, etc.: To avoid contamination of hands when removing gloves, initially remove contamination with a cotton swab soaked in a solution of the product or

with a napkin. Then perform glove treatment as described in the previous steps. Aer treatment with the product, remove the glove from the hands and dispose of it. Follow up with hygienic hand processing.

Hard surfaces and furniture with a small area in rooms: Disinfect by contact or irrigation. The consumption rate during contact is 50 ml/m². Processing is carried out once or twice. The maximum allowable area for processing should be no more than 1/10 of the total room area (e.g., for a 10 m² room, the surface to be disinfected should not exceed 1 m²). Surfaces, furniture, accessories, and sanitary-technical equipment are treated until completely wet or rubbed through abundantly with a wet wipe according to the modes shown in Table 1 of this instruction.

Surface Disinfection Procedure: Wet the surfaces to be disinfected completely and evenly across the entire plane. The product dries quickly without leaving traces on surfaces. Surfaces are ready for use after drying. If necessary, the surfaces can be rubbed with sterile tanzive wipes after the disinfection time, without waiting for them to dry.

Product Compatibility: The product is not suitable for use with low-quality or alcohol-based paints and varnishes, coated organic (acrylic) glass, and other unstable surfaces. Before use, check the effect of the product on a small, less visible area of the surface.

Biological Contamination: If biological contamination (organic and other) is present, remove it with a wet wipe. Perform a double treatment with another napkin according to the modes presented in Table 1 of this instruction. Dispose of wipes in the medical waste container for further use.

2.8. *Disinfection of Medical Devices and Equipment:* For medical devices and equipment, physiotherapy equipment, and diagnostic equipment that do not involve invasive intervention or direct contact with the patient's mucous membrane (e.g., USR sensors, mammograms, cardioelectrodes, etc.), disinfection of external surfaces of phonendoscopes and stethoscopes is carried out using a contact method with a heavily moistened napkin. Refer to the disinfection modes presented in Table 1 of this instruction. In the presence of biological products, the disinfection process is conducted in two stages in accordance with paragraph 2.8 of this directive.

2.9. *Disinfection of Non-Porous, Flat Materials:* For non-porous, flat materials such as wax pads, heaters, patient care items, toys, and other objects not considered biological products, rub them thoroughly with an abundantly moistened napkin, following the modes presented in Table 1 of this instruction.

In the presence of biological products, perform the disinfection process in two stages according to point 2.8 of this instruction.

2.10. *Disinfection of incubator surfaces* is carried out in accordance with SanPiN 2.1.3.2630-10 "Sanitary and epidemiological requirements for organizations engaged in medical activities" and recommendations of incubator manufacturers.

Disinfection of Cuvettes (with manufacturer's permission for alcohol-containing products): Disinfection of cuvettes' surfaces is carried out separately in a well-ventilated room in the absence of children. Spray the product at a distance of 30 cm onto the cuvette surfaces using a hand sprayer until completely wet or soak with the product solution using napkins. Allow a sanitizing period. After the prescribed time, rub the cuvette surfaces twice with sterile water using an abundantly moistened sterile cloth napkin (diaper). Aer each wash, dry the cuvette surfaces by wiping with napkins (underclothes). Ventilate cuvettes for 10 minutes.

2.11. Disinfection of Footwear Interior: For the interior of natural and artificial leather, plastic, and rubber shoes to prevent fungal diseases, perform the following steps: Rub the interior surfaces with two napkins soaked in the solution of the product, using one napkin for each shoe (per pair). Alternately, use a hand sprayer from a distance of at least 30 cm, irrigating evenly until the entire interior surface is completely wet. Allow the product to act for 2 minutes with a disinfection period.

Aer disinfection, washing of the product is not required. Ensure the shoes are dried before use.

2.12. Disinfection of Surfaces, Fixtures, Appliances, and Equipment in Buildings: For the external surfaces of structures to prevent plague, cholera, tularemia, and other particularly dangerous infections, follow the regimens presented in Table 1 of this instruction. Adhere to the recommended protocols for disinfection according to clauses 2.8.

2.13. Disinfection in Barbershops, Baths, Saunas, Swimming Pools, Sports Complexes, and Cosmetology Salons: Disinfection is recommended for dermatophytes using the modes specified in Table 1 of this instruction.

2.14. Disinfection in Ambulances, Civil Defense, and Emergency Services: Disinfection is conducted through irrigation or abundant moistening with napkins. Treated surfaces are ready for use immediately after the product dries. Disinfection is carried out as follows: During known infections, follow the recommended regimens in Table 1 of this instruction. For infections of unknown origin, especially viral infections, adhere to the appropriate regimens in Table 1 of this instruction. Preventive disinfection is conducted bacterially (excluding tuberculosis) using the recommended regimens during infections.

2.15. Disinfection in the Mortuary, Patho-Anatomical Service Buildings, Forensic Medicine Examination Institutions, Columbariums, Crematoria, Funeral Homes, and Other Funeral Service Providers: Conduct disinfection according to the modes specified in Table 1 of this instruction. Hearses undergo processing with modes suitable for sanitary transport, as outlined in clause 2.14 of this directive.

2.16. Disinfection of Structural Elements of Air Conditioners and Ventilation Systems, Fans, and Room Ventilation Systems: Surfaces of structural elements are irrigated and then subjected to friction or rubbing with a wet napkin. The consumption rate is as indicated in point 2.8 of the directive, following the regimens presented in Table 1 of this instruction.

Table 1. Disinfection modes of various objects

Disinfection material	Type of infection	Disinfection time, minutes	Method of disinfection
Small surfaces of furniture, furniture accessories, hard goods, sanitary transport objects, etc.	Bacterial (except tuberculosis) and fungal (candidiasis)	1	Irrigation or rubbing
	Dermatophytes	3	Irrigation or rubbing
	Special dangerous infections (plague, cholera, tularemia)	3	Pouring the solution on
	Bacterial (including tuberculosis), viral and fungal (candidiasis, dermatophytes)	5	Irrigation or rubbing
Surfaces of medical devices and equipment (USR sensors, mammograph, physiotherapy equipment, phonendoscopes, stethoscopes, etc.), dental terminals	Bacterial (except tuberculosis) and fungal (candidiasis)	1	Irrigation or rubbing
	Dermatophytes	3	Irrigation or rubbing
	Special dangerous infections (plague, cholera, tularemia)	3	
	Bacterial (including tuberculosis), viral and fungal (candidiasis, dermatophytes)	5	Pouring the solution on
Non-porous patient care items (thermometer, saucer, candle holder, stove, etc.), toys	Bacterial (except tuberculosis) and fungal (candidiasis)	1	Irrigation or rubbing
	Dermatophytes	3	Irrigation or rubbing
	Special dangerous infections (plague, cholera, tularemia)	3	Irrigation or rubbing
	Bacterial (including tuberculosis), viral and fungal (candidiasis, dermatophytes)	5	Pouring the solution on
Air conditioners and ventilation systems, including their structural elements, surfaces, fans, and room ventilation systems	Legionellosis	3	Irrigation or rubbing

3. RECAUTIONARY MEASURES

- 3.1. Individuals with chronic allergic reactions and pregnant women are not allowed to use the product.
- 3.2. The product is flammable. Avoid contact with open flames and connected heating devices. No smoking is allowed.
- 3.3. Store the product separately from drugs and food, out of reach of children.
- 3.4. Use the product only as intended, directly from the original package.
- 3.5. Do not use for the treatment of wounds and mucous membranes.
- 3.6. Avoid contact with the eyes when using the product.
- 3.7. Do not use the product after the expiration date or in case of improper storage.

4. FIRST AID MEASURES

- 4.1. In case of accidental spillage of the product into the eyes, immediately wash them with running water and drip 1-2 drops of a 20-30% sodium sulfacyl solution. If necessary, consult an ophthalmologist.
- 4.2. In the event of skin irritation or rash, stop using the product and wash hands with soap and water.
- 4.3. In the case of accidental ingestion of the product, rinse the mouth, drink several glasses of water, and induce vomiting. Then drink an adsorbent. If necessary, consult a doctor.
- 4.4. In the event of irritation of the respiratory organs, stop working with the product, take the victim to fresh air or a well-ventilated room, and ventilate the room. Drink a hot beverage. Rinse the mouth and nasal cavity with water. If necessary, consult a doctor.

5. PACKAGING, TRANSPORTATION, STORAGE

- 5.1. The product is packed in a consumer container in corrugated cardboard boxes or transported in polymer cubes.
- 5.2. The product is transported by all types of land transport, with closed vehicles, suitable for transporting cargo, and compliant with operational regulations for these vehicles to ensure the safety of the product. The transportation temperature is from plus 5°C to plus 30°C. It is allowed to transport, store, and use the product at a temperature of plus 5°C to plus 30°C within 3 (three) months.
- 5.3. The product is kept hermetically sealed by the manufacturer in packaging, in a dry place, at a temperature of plus 5°C to plus 30°C, away from heating devices, open flame, and direct sunlight.
- 5.4. In case of accidental spillage of a large amount of the product in an emergency situation, pour sand or earth over it (do not use flammable materials, such as sawdust), collect in a container with a lid for further use. Wash off the residue with plenty of water.
- 5.5. **Environmental protection measures:** Do not pour undiluted product into underground, surface water, wastewater, or sewer.
- 5.6. The shelf life of the product is 5 years from the date of production, under the conditions of keeping the product in tightly closed packaging.