

**METHODOLOGICAL INSTRUCTIVE REGULATIONS**  
**on the use of "DEFENS D2" product for disinfection of surfaces, household items, premises and public areas**

**1. GENERAL PROVISIONS**

**1.1. The full name of the product is a disinfectant "DEFENS D2", manufactured according to TU U 20.2-34774235-010:2020.**

**1.2. Manufacturing company - KAPITEL LKM LLC, Ukraine.**

**1.3. The product composition, the content of active and auxiliary substances:**

**DEFENS D2** - is a chloroactive, multi-component, multifunctional disinfectant with a washing effect.

**"DEFENS D2"** - is a disinfectant with a washing effect, a liquid of light colours with a faint smell of chlorine. It is supplied as a concentrate based on sodium hypochlorite.

Shelf life is 6 months. **"DEFENS D2"** water solutions are opaque, colourless, and have a faint smell of chlorine. Working solutions of the product have washing, disinfecting and pre-sterilizing properties, do not damage objects made of metal, glass, rubber, polymer materials, wood, tile, porcelain, earthenware and the surface of medical devices or equipment with paint, electroplating and polymer coatings, emulsify fats well, remove the protein-fat film from the treated surfaces, and can be easily washed off without residue.

**1.4. "DEFENS D2" intended use.**

**It is intended for:**

- current and final disinfection of health facilities and institutions, preschool institutions and centres of intestinal and drip infections of bacterial (including tuberculosis), fungal (candidiasis, dermatomycosis, mould fungi), viral (including influenza, parainfluenza, viral hepatitis, HIV, poliomyelitis, rotavirus infections) aetiology and particularly dangerous and zoonotic infections (plague, cholera, anthrax, etc);
- pre-sterilization cleaning and combining the processes of disinfection and pre-sterilization cleaning of medical devices made of corrosion-resistant metal, glass, rubber, polymer and combined materials;
- decontamination of single-use medical devices and used dressings before their disposal;
- preventive disinfection and carrying out routine or general cleaning in health care institutions of various areas (surgical, therapeutic, urological, nephrological, ophthalmological, obstetric, gynaecological, children's, anti-tuberculosis, infectious, physiotherapy, pathoanatomic and other departments, dental clinics, polyclinics, outpatient clinics, paramedic-obstetric centres, blood service institutions, clinical, biochemical, bacteriological, serological and other specialized diagnostic laboratories, stations and mobile emergency medical care, donor and blood transfusions stations, medical units and sanitary stations, etc.) and pharmacies;
- preventive disinfection and carrying out routine or general cleaning in diagnostic and testing laboratories of various areas;
- preventive disinfection and carrying out routine or general cleaning in health facilities (sanatoriums, dispensaries, rest homes, boarding houses, etc);
- preventive disinfection and carrying out routine or general cleaning in preschool institutions, educational and cultural institutions;
- preventive disinfection and carrying out routine or general cleaning in establishments of restaurant economy and trade;
- preventive disinfection and carrying out routine or general cleaning in sports and health facilities;
- preventive disinfection and carrying out routine or general cleaning in social service institutions, penitentiary institutions;
- preventive disinfection and carrying out routine or general cleaning at communal facilities (hotels, campsites, dormitories, hairdressers, cosmetology clinics and salons, tanning salons, laundries, baths, saunas, public toilets, etc);
- preventive disinfection and carrying out routine or general cleaning at water supply and sewerage facilities;
- preventive disinfection and carrying out routine or general cleaning of train and passenger transport facilities (including railway, air transport, water transport, road transport, underground transport) and vehicles for the transportation of food and raw materials;
- preventive disinfection and carrying out routine or general cleaning at home and at epidemic-significant objects of other industries and services, the activities of which require disinfection measures under the current sanitary-hygienic and anti-epidemic rules and regulations, regulatory and methodological documents;
- sanitation (washing and disinfection) of perfumery and cosmetics enterprises, pharmaceutical and microbiological industries;
- sanitation (washing and disinfection) of the food and processing industry, agricultural objects.

**1.6. Specific biological properties of the product: "DEFENS D2"** has bactericidal (including tuberculocidal), virucidal (against pathogens of polio, influenza of all types, parainfluenza, coronavirus, respiratory syncytial, rotavirus, adenovirus infections, SARS, hepatitis, HIV, viral gastroenteritis, etc.), sporicidal and fungicidal (including pathogens of candidiasis, dermatomycosis, mould fungi) properties. **"DEFENS D2"** working solutions homogenize sputum and other secretions have moisturising, emulsifying and washing properties, effectively remove mechanical, protein, fat contamination, blood, secretions and drug residues from the external surfaces, internal channels and voids of medical devices.

**1.7. The toxicity and safety of the product: "DEFENS D2"** under the requirements of GOST 12.1.007 belongs to moderately dangerous substances (hazard class 3) when introduced into the stomach and inhaled into the body and to low-hazard substances when applied to the skin (hazard class 4). Under the conditions of inhalation exposure in the form of vapours, according to the degree of volatility, it belongs to low-hazard substances. In dry form and concentrated solutions, it irritates the mucous membrane of the eyes and upper respiratory tract. In the concentrations recommended for washing and disinfection, it does not have skin-irritating properties, does not irritate the mucous membrane of the eyes. The product does not have skin-resorptive and sensitising, carcinogenic, mutagenic and embryotoxic (according to the active substance) properties.

**2. WORKING SOLUTION PREPARATION**

**2.1. Methods and conditions for preparing working solutions: "DEFENS D2"** working solutions are prepared in a marked container made of any materials, except for galvanized iron, by dissolving in the water while stirring for 1-2 minutes. Drinking water is used in the preparation of product working solutions. When preparing the working solutions of 0.5-2.5% concentration, it is advisable first to prepare a suspension of the product in a small amount of water, and then bring it to the calculated volume with water. It is allowed to use hot water at a temperature of (60±5) °C to

prepare 0.5-2.5 % solutions of the product to accelerate its dissolution in water.

**2.2. Calculations for preparing the working solution:** the calculations shown in Table 1 shall be considered for the "DEFENS D2" working solutions preparation of the appropriate concentration.

Table 1. Calculations for preparing the working solution

Concentration % (for the product)	1 litre of solution		1000 litres of solution	
	Amount of product, l	Volume of water, l	Amount of product, l	Volume of water, l
1	0.100	0.900	100	900

### 2.3. Working solution shelf life and storage conditions:

"DEFENS D2" working solutions are prepared directly before use. It is allowed to store the unused working solution for 3 days after preparation in a container with a tightly closed lid. It is allowed to use the unused working solution for pre-sterilization cleaning of medical devices and carrying routine and general cleaning within 14 days from the date of the preparation.

"DEFENS D2" solutions are used for the disinfection purpose once.

## 3 DISINFECTION PURPOSE APPLICATION METHODS

**3.1. Objects of application:** "DEFENS D2" is used for disinfection and washing of the following objects:

- medical devices (including endoscopes and instruments for them) made of corrosion-resistant metals, glass, silicone-based and natural rubber, polymer and combined materials;
- medical and other devices, apparatus, equipment with electroplating, paint, polymer and combined coating, as well as made of glass and rubber;
- patient care items (pads, ice bags, hot water bottles, etc.) and personal hygiene items (combs, sponges, etc.);
- excrements (urine, faeces, sputum, etc);
- linen;
- tableware (dining, kitchen, pharmacy, laboratory);
- tanks and reservoirs for drinking water;
- toys;
- surfaces in premises (floor, walls, doors, window frames and glass, window sills, etc.), furnishings (hard and soft furniture, carpets);
- pharmacies equipment;
- equipment and packaging of food units of health care institutions and preschool institutions;
- sanitary-technical equipment;
- medical waste (including single-use items made of various construction materials, dressings, cotton and gauze swabs, gauze napkins, etc.) before disposal;
- means of transport;
- cleaning equipment;
- containers for collecting, accumulating, storing waste and garbage;
- technological equipment, product lines, inventory, containers of pharmaceutical, microbiological, perfume and cosmetics, food and processing industries,
- hairdressing, manicure and cosmetology tools;
- ventilation systems, air conditioners.

**3.2. Individual objects decontamination methods with the product:** disinfection of objects shall be performed by irrigation, wiping, soaking, dipping, volumetric and filling with native powder under the modes shown in Tables 2-7.

**3.2.1. Medical devices made of corrosion-resistant metals, glass, rubber, polymer and combined materials** shall be disinfected by submerging into a working solution of the appropriate concentration. The depth of the working solution layer over the submerged medical devices must be at least 1 cm. Detachable products that have cavities and channels (syringes, etc.) shall be disinfected in the disassembled state. Channels and cavities shall be filled with a working solution completely using continuous type syringes or an electric pump. The container with submerged medical devices in the solution shall be closed tightly with a lid. After the disinfection of medical products, they shall be rinsed with running drinking water and then with distilled water. The channels and cavities shall be washed by pumping running drinking water through them using a continuous type syringe or an electric pump. For medical devices and their parts that have no direct contact with a patient, a method of twice wiping with napkins (cleaning cloth) moistened with a working solution with an interval of 15 minutes and following the exposure is allowed. Medical devices shall be rinsed with running water for 3 minutes after disinfection. To wash the internal channels and cavities of medical devices, water shall be pumped through them using a continuous type syringe or an electric pump.

**3.2.2. Linen** (underwear, bedclothes, mattress covers, bags for linen, etc.) shall be completely submerged in a working solution by piece at the rate of 4 l/kg of dry linen (for cholera, 5 l/kg of dry linen). The container with the laundry submerged in the working solution shall be closed tightly with a lid. After disinfection, the laundry shall be washed and rinsed.

**3.2.3. Tableware** shall be cleaned from the contents (food residues, biological material, excrements, nutrient media, reagents, etc.) and completely submerged in the working solution. The consumption rate of the working solution is 2 l/set (cup, saucer, deep and small plates, teaspoon and tablespoon, fork, knife). Laboratory utensils (flasks, cylinders, test tubes, pipettes, etc.) shall be filled with a working solution. The container with the tableware submerged in the working solution shall be closed tightly with a lid. After disinfection, the dishes shall be washed with a brush and rinsed twice with water (preference should be given to warm water at a temperature of  $(45 \pm 5) ^\circ\text{C}$ ).

**3.2.4. Toys** shall be completely submerged in the working solution (you need to make sure that the toys do not pop up). After the exposure is complete, they shall be washed twice with water until the chlorine smell is completely removed. Large toys shall be wiped with a cleaning cloth moistened with a working solution. Soft toys shall be cleaned with a brush moistened with a working solution. After disinfection, the toys shall be rinsed with running water until the chlorine smell is completely removed.

**3.2.5. Surfaces in premises** (floor, walls, doors, window frames, etc.) and furnishings shall be wiped with cleaning cloth moistened with a working

solution (the consumption rate is 100 ml/m<sup>2</sup> of the surface) or irrigated with special equipment (the working solution consumption rate during the disinfection of surfaces in premises by irrigation method depends on the type of device used and information specified in the device technical documentation). After surface treatment with a working solution of the product, maintain the set exposure and thoroughly ventilate the premises for 15 minutes.

**3.2.6. Surfaces of sanitary equipment** shall be irrigated with a working solution or wiped with a cleaning cloth or brush moistened with a working solution twice with an interval of 15 minutes. The working solution consumption rate is 100 ml/m<sup>2</sup> of the surface when disinfecting sanitary equipment by wiping. In the case of sanitary equipment disinfection by irrigation, the working solution consumption rate is specified in the normative document for special equipment used. It is allowed to disinfect the sanitary equipment surfaces by cleaning with a powdered product that is applied to a brush or cleaning cloth. After applying the working solution or native agent to the surface of sanitary equipment, maintain the established exposure and wash the sanitary equipment with running water until the smell of chlorine is removed.

**3.2.7. Medical and other devices, equipment with paint, electroplating, polymer and combined coating, as well as made of rubber and glass** shall be wiped with a cleaning cloth moistened with a working solution twice at intervals of 15 minutes, followed by compliance with the appropriate exposure. Parts of medical and other devices, and equipment that are subject to contact with the skin of patients, after disinfection, shall be wiped with napkins moistened with drinking water.

**3.2.8. Working (internal) surface** of small-size vessels technological equipment of pharmacies and pharmaceutical and microbiological industry not equipped with cleaning heads shall be cleaned mechanically from the remnants of raw materials, semi-finished and finished products, washed with water, filled with the working solution (volumetric method of disinfecting) and maintained under the established exposure. After the end of the exposure, the working solution shall be drained and the object shall be rinsed with water for 3 minutes to remove the remnants of "DEFENS D2".

**3.2.9. Technological tanks of pharmacy institutions and enterprises of the pharmaceutical and microbiological industry** equipped with washing heads shall be pre-cleaned from the remains of raw materials, semi-finished and finished products with water at a pressure of 6-8 kgf/cm<sup>2</sup> (0.6-0.8 MPa) for 30 minutes. The working solution shall be applied to the surface of the tank with the help of washing heads and maintained for the set exposure, washed with cold water under pressure until the remaining product is completely removed.

**3.2.10. Mixers of pharmacy institutions and enterprises of the pharmaceutical and microbiological industry** shall be disinfected by filling the internal volume with 1/3 of the volume of working solution, then the mixer shall be activated 2-5 times for 3-5 minutes during the set exposure. After stopping the mixer, the spent working solution shall be drained and the inner surfaces shall be rinsed with water for 3 minutes until the remaining "DEFENS D2" is removed completely. After that, it should be air-dried.

**3.2.11. Disinfection of patient care items** shall be performed by irrigation, submerging in a working solution or wiping with a cleaning cloth moistened with a working solution. After disinfection, patient care items shall be rinsed with running water until the chlorine smell is completely removed.

**3.2.12. Cleaning equipment** shall be submerged in the working solution. After disinfection, it shall be rinsed with running water until the chlorine smell is completely removed and dried in the air.

**3.2.13. Medical waste** (dressing material, cotton and gauze swabs, napkins, single-use underwear, single-use medical products, etc.) shall be submerged in the working solution of the product in a specially marked container, which is tightly closed with a lid for the period of disinfection. After disinfection, medical waste shall be disposed of.

**3.2.14. General and routine cleaning of premises** shall be performed by wiping or irrigation methods. During general cleaning, first, you must move furniture and equipment away from the walls. After cleaning, the room shall be ventilated.

#### 4 PRECAUTIONS WHEN WORKING WITH THE PRODUCT

**4.1. Necessary skin, respiratory and eye protection when working with the product.** People working on the preparation and application of "DEFENS D2" working solutions by irrigation method shall have personal protective equipment for the skin, respiratory organs and eyes — an overall, a cap, an apron made of rubberized fabric, rubber gloves, special shoes, protective glasses type PO-2, PO-3 or monoblock, a petal-type respirator mask.

**4.2. General precautions when working with the product.** People under the age of 18, pregnant women, breastfeeding women and those who have an increased sensitivity to the product components are not allowed to perform work with "DEFENS D2". Persons who have skin damage in the form of scratches, wounds and irritations in open areas of the body that are accessible to the action of the disinfectant or its working solutions are not allowed to work with the product. It is forbidden to eat or smoke while performing disinfection work. When the disinfection work is completed, wash your face and hands with soap and water. Clothing contaminated with the product should be removed and washed before reuse.

**4.3. Precautions when preparing working solutions.** The staff preparing the working solutions must be provided with means of individual protection of the skin, respiratory and eye — an overall, a cap, an apron made of rubberized fabric, rubber gloves, rubber shoes, safety glasses type PO-2, PO-3 or monoblock, a petal-type respirator mask.

**4.4. Safety precautions for the treatment of individual objects.** When using "DEFENS D2" solutions by irrigation and wiping methods, the active substance (sodium hypochlorite) in the indoor human respiratory air zone is not determined within the sensitivity of the measurement method. The content of the hydrolysis product of the active substance (free chlorine) in the air does not exceed the ambient air standard for the atmospheric air of populated areas. It is allowed to disinfect surfaces of premises, furniture, equipment with 0.1-0.2 % "DEFENS D2" solutions by wiping, as well as disinfection of objects with solutions of "DEFENS D2" by immersion in a container with a tightly closed lid in the presence of patients and other persons not directly involved in carrying out disinfection measures. Preventive disinfection in preschool institutions through wiping and irrigation with working solutions "DEFENS D2" shall be performed in the absence of children, followed by airing the room for 30 minutes.

**4.5. Product disposal methods.** "DEFENS D2" used working solutions in concentrations of 1.0 % are poured into the sewer system, working solutions of higher concentrations are diluted with water before being drained into the sewer.

#### 5. ACUTE POISONING SIGNS. FIRST AID MEASURES FOR POISONING

**5.1. Acute poisoning signs.** Symptoms of eye irritation and upper respiratory tract irritation are tear secretion, swelling and conjunctival hyperaemia, throat flap, cough.

**5.2. First-aid measures for acute (respiratory) poisoning with the product.**

If the respiratory tract is affected, it is necessary to get the affected to fresh air or a well-ventilated room, keep at rest, provide warmth, and loosen any tight clothing. The affected person is recommended to drink milk.

**5.3. First-aid measures in case of contact with eyes.** In case of accidental contact with the eyes, rinse them with running water for 10-15 minutes. If the mucous membrane of the eyes is irritated, it is recommended to drop 1-2 drops of sodium sulfacyl (albicide) in the eyes and see a doctor.

**5.4. First-aid measures in case of skin contact:** Wash the contaminated skin area with running water. If the product gets on work clothes, remove it, and the skin area under the clothing shall be thoroughly washed with running cold water.

**5.5. First-aid measures in case of contact with the stomach.** If the product accidentally enters the stomach, the affected person shall drink several glasses of cold water and induce vomiting. The affected person is recommended to drink milk.

**5.6. Product neutralization.** The product remnants on objects in the human life and activities environment are neutralized with a 1.0 % solution of sodium thiosulfate.