

## METHODOLOGICAL INSTRUCTIVE REGULATIONS

### on the use of "DEFENS D1" for disinfection of hands, skin, surfaces and noncritical medical devices

#### 1. GENERAL PROVISIONS

**1.1. The full name of the product** is a disinfectant "**DEFENS D1**", according to TU U 20.2-34774235-010:2020.

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

**1.3 The composition of the product, the content of active and auxiliary substances:** isopropyl alcohol - not less than 70,0%, benzalkonium chloride - 0,15%, glycerine, distilled water up to 100%.

**1.4. Product form and physical and chemical properties.** The product "**DEFENS D1**" is available as a ready-to-use liquid with a smell of alcohol, pH is  $5.5 \pm 1.5$ . Does not contain dyes. Glycerine protects hands and skin from dryness and irritation, preserves elasticity and natural water-fat balance of the skin.

**1.5. "DEFENS D1" intended use.** It is intended for:

- hand disinfection (sanitization) of healthcare institutions medical personnel.
- hygienic disinfection (sanitization) of laboratory personnel hands of different subordinates (clinical and diagnostic, microbiological, biochemical, bacteriological, serological, etc.), sanitary transport (including ambulances), in donor blood transfusion points, medical units, paramedic-obstetric and medical centres;
- hygienic disinfection (sanitization) of the public service facilities personnel hands (hairdressers, beauty salons, SPA centres, manicure centres, pedicure centres, massage rooms, cosmetology clinics, salons, tanning salons, baths, saunas, etc.) before and after working with the client, as well as for the treatment of clients' skin during a manicure, pedicure, tattooing, piercing and other procedures related to skin damage; for disinfection (sanitary treatment) of the skin, treatment of foot skin to prevent fungal and other infections;
- hygienic disinfection (sanitization) and decontamination of the personnel hands skin of the food processing industry (bakeries, confectionery factories, dairies, meat, beer, soft drinks, mineral water processing plants etc.), enterprises and institutions of the agro-industrial complex (dairy farms, poultry farms, etc.), perfume and cosmetics, pharmaceutical, chemical, biotechnological, microbiological industry; for disinfection (sanitization) of the hands of staff and visitors of public catering and trade establishments (canteens, restaurants, fast food restaurants, shops, supermarkets, markets);
- hygienic disinfection (sanitization) of hands and antiseptic treatment of skin at home when caring for patients, infants, the elderly people, while travelling, in places of high infectious danger;
- hygienic hand disinfection (sanitization) of staff and children of pre-school institutions, staff and students of educational institutions of different accreditation levels, disinfection, sanitary-epidemiological and veterinary services workers, pharmacies and pharmaceutical institutions, health resort, sports and health institutions in various fields, social welfare institutions (nursing homes, houses of the disabled), communication institutions and banking facilities; hand disinfection (sanitization) of staff and passengers of all means of transport (including rail transport [in passenger cars and other trains, railway stations] and air transport), facilities and units of the Ministry of Internal Affairs and Ministry of Defence, in penitentiary institutions, customs officials, border services and other facilities, operation of which requires compliance with sanitary and hygienic norms and rules;

The product is intended for use in the following areas:

health institutions, laboratories of different subordination, pharmaceutical institutions, food processing industry, catering industry and trade industry (including shopping), public utility facilities (including public transport, common areas), enterprises of pharmaceutical, chemical, biotechnological, microbiological, perfumery and cosmetics industry, sports facilities, recreation and entertainment facilities, social protection institutions, military units, offices and banking institutions, educational and training institutions, preschool institutions, transport (rail, road, air, underground, river, sea, etc.),

#### 1.6. Product-specific biological properties: antimicrobial spectrum.

"DEFENS D1" has antimicrobial activity against gram-positive and gram-negative bacteria (including pathogens of nosocomial infections, Mycobacterium tuberculosis, multi-resistant Staphylococcus (MRSA), enterohemorrhagic Escherichia coli, Pseudomonas aeruginosa, Salmonella and other antibiotic-resistant bacteria), viruses (incl. parenteral viral hepatitis (B, C), AIDS virus (HIV), papovaviruses, adenoviruses, polyomaviruses, polioviruses, noroviruses, rotaviruses, enteroviruses, vaccinia viruses, SARS, herpes viruses, influenza viruses, influenza A virus (H5M1), influenza A virus (H1N1), etc.), pathogenic fungi (incl. pathogens of candidiasis, dermatomycosis, trichophytosis).

The product is highly effective against transient and resident microflora, which provides high-quality hygienic and surgical antiseptics of hands and skin. The product shows high-quality action in the presence of protein, serum, blood. The product provides an antiperspirant effect, reduces the amount of moisture under the gloves, which prevents the release of resident microflora. The product "**DEFENS DI**" has a prolonged (remnants, residual) antimicrobial effect for 3 hours (including under medical gloves).

The product provides a degreasing skin cleansing, promotes effective adhesion of the surgical film.

**1.7. Product toxicity and safety.** "**DEFENS DI**" in terms of acute toxicity belongs to low-hazard substances (under the requirements of GOST 12.01.007 76) when introduced into the stomach and when applied to the skin (class 4). It has no skin-irritant and sensitizing properties when applied once and repeatedly on the skin. Applying the product to scarified skin does not complicate the healing of artificially applied wounds. The product has no cumulative properties, specific **long-term effects** (mutagenic, embryotoxic, gonadotropic, teratogenic **and** carcinogenic).

## 2. WORKING SOLUTION PREPARATION

**2.1. Methods and conditions for preparing working solutions.** "**DEFENS DI**" is a ready-to-use disposable product that is used undiluted.

## 3. DISINFECTION PURPOSE APPLICATION METHODS

**3.1. Application objects.** The product "**DEFENS DI**" is used for hygienic and surgical hand disinfection (sanitization) of all health care institutions medical and nursing staff, for rapid disinfection of surfaces of medical products, including non-critical instruments, gloves and other objects, for hygienic hand and skin disinfection at home, treatment of the foot skin to prevent fungal and other infections, for hygienic disinfection and decontamination of personnel hands of various areas specified in section 1.5.

### 3.2. Objects decontamination methods with the product.

**3.2.1. Hygienic disinfection (sanitization) and decontamination** of hands are directed against the acquired pathogenic microflora (transient flora). To interrupt the infectious diseases transmission chain, it is recommended to perform hygienic disinfection (decontamination) before washing hands. For accurate hygienic dosing of the product and to avoid the risk of cross-infection, it is recommended to use wall-mounted elbow dispensers, medfix or wall-mounted holders.

Before any manipulations, apply 3 ml of "**DEFENS DI**" product on dry hands and rub it for 15 seconds.

#### After manipulations:

*in case of uncontaminated hands*, apply 3 ml of "**DEFENS DI**" product on dry hands and rub it for 15 seconds;

*in case of contaminated hands*, remove the contamination from hands with a disposable napkin, and then treat your hands by rubbing 3 ml of "**DEFENS DI**" product for 15 seconds. Hand treatment technique should be adhered to during the hygienic disinfection (decontamination) of hands. After disinfection, there is no need to wash, wipe or dry your hands.

**3.2.2. Rapid disinfection of surfaces, medical devices, including noncritical tools, gloves and other objects** shall be carried out by wiping or spraying (if there is a spray) objects with the "**DEFENS DI**" product, keeping the surface (item, tool, etc.) moistened for 15 seconds. The consumption rate of the product should not exceed 30 ml/m<sup>2</sup>. After the end of the exposure time, it is not necessary to wash off the product.

## 4. PRECAUTIONS WHEN WORKING WITH THE PRODUCT

### 4.1. Necessary skin, respiratory and eye protection when working with the product.

Does not require skin, respiratory or eye protection

**4.2. General precautions when working with the product.** The "**DEFENS DI**" product is intended for external use only. Do not use for the treatment of mucous membranes, do not allow the product to come in contact with the eyes. The product is dangerous if swallowed, so you should avoid getting it into the stomach. The product is inflammable, it is forbidden to perform disinfection work in premises if there are sources of open fire and heat. In case of accidental spilling of a large amount of product, provide intensive ventilation of the room. Spilt product is collected with sand or other non-flammable material that absorbs the liquid well. The cleaned surface is washed with water.

**4.3. Disposal methods.** The expired batches of "**DEFENS DI**" or unconditional batches due to violation of storage conditions are subject to return to the manufacturer for processing.

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

**5.1. Acute poisoning signs.** No data are available.

**5.2. First-aid measures for acute (respiratory) poisoning with the product.** Not available.

**5.3. First-aid measures in case of contact with eyes.** Rinse eyes with a large amount of water. When necessary, seek medical advice.

**5.4. First-aid measures in case of contact with the stomach.** It is recommended to rinse the oral cavity with water and drink a large amount of water. Do not induce vomiting! If necessary, seek medical advice.

## 6. PACKAGING. TRANSPORTATION. STORAGE

**6.1. Packaging of the product.** The "DEFENS D1" product is packed in 5 litres to 20 litres cans, as well as in 50 ml to 1-litre containers with dispensers, the range of packaging can be changed or supplemented by agreement with the manufacturer.



70 ml.



5 litres to 20 litres cans.



1 litre

**6.2. Transportation conditions.** Transportation of the product is carried out in the manufacturer's packaging by all means of transport under the rules of transportation of this category of cargo.

**6.3. Storage terms and conditions.** The "DEFENS D1" product is stored in the manufacturer's sealed package at a temperature of +5°C up to +30°C in indoor unheated warehouse premises, protected from moisture and direct sunlight, away from open fire and heat sources, separate from flammable materials and substances, in places inaccessible to children. Storage facilities must be provided with one of the fire extinguishing means. The expiration dating period of the product is 3 years from the date of manufacture.

## 7. QUALITY CONTROL METHODS OF THE PRODUCT

### 7.1. Controlling indicators and norms.

The disinfectant "DEFENS D1" is controlled by the following quality indicators: appearance, colour, smell, hydrogen index (pH).

### 7.2. Determination of appearance, colour and smell.

The appearance and colour of the product are determined visually. The product is made in the form of a transparent agent.

The smell is evaluated by an organoleptic method.

### 7.3. Determination of the hydrogen index (pH) of the product.

The hydrogen ions (pH) concentration is determined by the potentiometric method under SP (State Pharmacopoeia) XI, 1 edition, page 113 "Determination of pH".