

INSTRUCTION No 01/13 dated 12.03.2013

for use of **DEZIN** anti-infective agent (**skin antiseptic**)
(OOO Dezindustrya, Russia)

The Instruction is executed by:

the Scientific Research Institute of Disinfectology of the Ministry of Health of Russia (SRID) – bacterial, fungicidal, virucidal activity, toxicity studies; the Central Research Institute of Epidemiology of the Ministry of Health of Russia (CRIE) – chemical and analytical studies;

Moscow City Centre of Disinfection ILC GUP¹ (MCCD ILC GUP) – tuberculocidal activity (tested on *Mycobacterium terrae*);

OOO Dezindustrya – formulation, quality control methods, storage stability, packing.

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This Instruction is executed in supersession of the Instruction for use of Dezin agent No D-01 dated 11.05.2004.

1. GENERAL INFORMATION

1.1. **DEZIN** anti-infective agent (skin antiseptic) (hereinafter – **DEZIN** agent) is a clear or opalescent liquid with a colour range from achromatic to light-yellow and a light scent. Fine sediment is acceptable during storage. The agent contains Chlorhexidine bigluconate 20% as the active ingredient. The agent mixes well with water and alcohol.

The shelf life of the agent amounts to 5 years from the manufacture date in an unopened manufacturer's container.

The shelf life of the working solutions in a tightly closed container cannot exceed 14 days.

1.2. **DEZIN** agent:

– as water-alcohol solutions has antimicrobial activity toward gram-negative and gram-positive bacteria (including *Mycobacterium tuberculosis* – tested on

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Mycobacterium terrae), Candida and Trihophyton fungi, viruses (including enteral and parenteral hepatitis viruses (hepatitis A, B and C), HIV, poliomyelitis, adenoviruses, SARS viruses, «avian» influenza A/H5N1, «swine» influenza A/H5N1, influenza, herpes viruses etc.);

– as water solutions has antimicrobial activity toward gram-negative and gram-positive bacteria (except Mycobacterium tuberculosis), Candida and Trihophyton fungi.

1.3. When injected gastrically or applied to skin, **DEZIN** agent is included in class 4 low-hazard compounds by the acute toxicity characteristics according to GOST 12.1.007-76 classification. When injected abdominally, the agent is included in class 4 low-toxic substances according to K.K.Sidorov's classification. The agent does not have a local irritative effect on the skin with a single application; the water-alcohol and water solutions of the agent do not have an irritative effect on the skin with a repeated application. The agent is low-hazard in case of inhalation exposure to its vapor in a saturating concentration. Both the agent and the working solutions have an irritative effect on the conjunctivae.

The Safe Reference Level of Impact in the working area of Chlorhexidine bigluconate 3mg/m³, aerosol.

1.4. **DEZIN** agent as **water-alcohol solutions** is intended for:

– the hand hygiene of medical personnel at medical and preventive treatment facilities (dental, pharmaceutical, pharmacies and other healthcare facilities including outpatient and inpatient facilities, organ transplant centres, core medical facilities, blood transfusion service, maternity hospitals, delivery departments, children's units, neonatal centres and departments); facilities engaged in license-based private medical practice; in sanitary inspection rooms; effective disease areas; all types of medical transport (including ambulance and Civil Defense and Emergency Situations vehicles); clinical and diagnostic laboratories (bacteriological, virological, mycological, immunological, clinical etc.);

– the hand hygiene of surgeons, instrument nurses and other specialists involved in surgical interference in the organizations conducting medical activities (including dental clinics) as well as of those involved in delivering in maternity hospitals etc.;

– the disinfection of the injection and surgical sites prior to invasive intervention, procedures, manipulations (including injections, therapeutic and exploratory punctures, catheterization of peripheral and central vessels, spinal punctures, epidural space catheterization, joint punctures, blood transfusion etc.), as well as during

transportation in ambulance vehicles and in emergency situations;

– the treatment of donors' elbow bends in medical and preventive treatment facilities and at blood transfusion stations;

– the disinfection of medical appliances (including surgical and dental instruments, rigid and flexible endoscopes, endoscopic instruments) in general medical and preventive treatment facilities;

– the disinfection of hard-to-reach small-area surfaces indoors: floor coatings; hard furniture, mattresses, headrests, armrests etc.; heating radiators etc.; lighting equipment, blinds etc.; external surfaces of medical appliances and equipment (including those of artificial respiration machines and anaesthesia equipment); equipment and surfaces in medical transport after the transportation of a contagious patient; tables (including surgical, manipulating, changing, delivery ones); gynaecological and dental chairs, beds, anti-decubitus mattresses etc.; telephones, monitors (except LCD monitors), computer keyboards and other office equipment.

DEZIN agent as **water solutions** is intended for:

– the disinfection of indoor surfaces (floor, walls), hard furniture, external surfaces of machines, appliances, sanitary equipment in case of infections of bacterial (except tuberculosis) and fungal aetiology (candidiasis and dermatomycosis) in organizations conducting medical activities, including medical and preventive treatment facilities, in communal buildings, daycare centres etc.

– preventive disinfection at community service facilities, in shopping and entertainment centres, at public dining and trading facilities (restaurants, bars, cafés, canteens), food and industrial markets, in educational institutions (including preschool), at cultural and recreational facilities, (balneology and sports facilities, offices, cinema theatres, museums etc.), at military establishments (including barracks), detention facilities, social security facilities (disabled persons and residential care homes, etc.).

2. PRODUCING WATER SOLUTIONS

DEZIN agent used as water and water-alcohol solutions is mixed in a vessel of any material in line with the estimates in Table 1.

Water-alcohol solutions are produced of 96% ethyl alcohol and water: distilled water – for further use as skin antiseptic and drinking water – for further use as disinfectant of medical appliances and surfaces.

Water solutions of the agent are produced of drinking water.

Production of **DEZIN** agent working solutions

Table 1

Working solution type	Working solution concentration by AI (Active Ingredient), %	Quantity of ingredients (ml) for 1 litre working solution		
		solution	water	96% ethyl alcohol
Water	0.2	10	990	–
Water-alcohol	0.1	5	265	730
	0.5	25	245	730

3. APPLICATION OF DEZIN AGENT WATER-ALCOHOL SOLUTIONS

3.1. Hand hygiene: **0.5%** agent water-alcohol solution (**5 ml**) is applied to dry hands (without prewashing them with water and soap) and rubbed into the skin until dry for at least **2 minutes**, treating the skin between the fingers and at the fingertips thoroughly.

3.2. The hand hygiene of surgeons, instrument nurses, obstetricians and other specialists involved in performing surgeries and deliveries: before the agent is applied, the hands and forearms are washed with warm running water and toilet soap (hard or liquid) for two minutes and dried with a sterile gauze pad. Then **0.5%** water-alcohol solution (**5 ml**) is applied to the hands and rubbed into the skin of the hands (palmar and dorsal surfaces, web spaces of both hands, paying particular attention to the fingertips and the periungual areas) and the forearms for **1.5 minutes**; then **0.5%** agent water-alcohol solution (**5 ml**) is applied again to the hands and rubbed into the skin of the hands and forearms for **1.5 minutes** keeping the hands wet during the entire time of the treatment. The gross treatment time is **3 minutes**. Sterile gloves are put on the hands after the agent has completely dried up.

The agent has a prolonged effect for 3 hours.

3.3. Skin treatment in surgical sites, donors' elbow bends, before insertion of a catheter and a joint puncture: the skin is rubbed with double-split gauze sponges amply saturated with **0.5%** agent water-alcohol solution. Waiting time after the end of the treatment is **2 minutes**. The patient takes a shower (bath) and changes the underwear the day before the surgery.

3.4. Injection site treatment: the skin is rubbed with a sterile cotton ball amply saturated with **0.5%** agent water-alcohol solution. Waiting time after the end of the treatment is **1 minute**.

3.5. Manual disinfection of medical appliances is performed in a plastic or enamelled

(without enamel defects) container with a lockable cover using **0.5% DEZIN** agent water-alcohol solution.

Disinfection guidelines for medical appliances are presented in Table 2.

3.5.1 Medical appliances must be fully immersed in the agent working solution right after their usage to ensure immediate removal of visible contamination from their surfaces with a cloth. Used cloths are placed in a separate container, disinfected and then disposed of.

The cavities and hollows of medical appliances must be filled with the solution, making sure there are no airlocks. The cavities are pumped through with the agent solution and blown through with air alternately using a syringe or another appliance. The procedure is repeated several times until the biogenic contamination is completely removed.

Built-up appliances must be immersed in the solution in a disassembled state. Appliances with locking parts must be immersed in an open state after a few working motions for better solution penetration into the tight areas of the locking parts of the appliances. The agent layer over the appliances must be at least 1 cm thick.

After the end of the disinfection waiting period, the appliance is removed from the container and rinsed free from the agent residuals with running drinking water for at least 5 minutes, paying particular attention to cleaning the cavities (using a syringe or an electric suction machine) and making sure the used water does not leak into the container where the appliances are being cleaned.

3.5.2. The disinfection of rigid and flexible endoscopes and endoscopic instruments with 0.5% **DEZIN** agent water-alcohol solution must be performed in accordance with the sanitary and epidemiological rules Sanitary Rules (CII) 3.1.1275-03 «Infectious Disease Prevention in the Process of Endoscopic Manipulations», Procedural Guidelines (MY) 3.5.1937-04 «Cleanup, Disinfection and Sterilization of Endoscopes and Endoscopic Instruments», as well as with the recommendations of endoscopic equipment manufacturers.

*Attention! **DEZIN** agent can be applied to endoscopes only if their manufacturer allows using alcohol-containing agents for these purposes.*

Precleaning is particularly important when using **DEZIN** agent. The equipment is treated immediately after endoscopic manipulations (it is recommended not to let the biological contamination dry up). The guidelines below must be strictly followed:

Visible contamination is removed from the external surface and the lens of an endoscope using a cloth (gauze pad) saturated with the agent solution moving from

the control body all the way to the distal end.

The valves and plugs are detached from the endoscope and immediately immersed in the agent solution ensuring full surface contact with the solution. All the channels of the endoscope are cleaned by pumping through the agent solution and the air alternately until the visible biogenic contamination is completely removed.

Medical appliances are fully immersed in the working solution so that it fills their cavities and hollows and left to soak.

After the soaking, the appliances are cleaned in the same solution using special tools until all the channels are totally clean.

Endoscopes and endoscopic instruments are rinsed first with running drinking water for 5 minutes and then with distilled water for 1 minute.

Disinfection guidelines for medical appliances (MA) using DEZIN agent water-alcohol solution.

Table 2.

Disinfection objects	Infection aetiology	Disinfection modes		Disinfection method
		Working solution concentration by AI (Active Ingredient), %	Disinfection time, min.	
Medical appliances of various materials (metal, rubber, plastic, glass etc.), including surgical and dental instruments, instruments with locking parts, endoscopic instruments	Bacterial (including tuberculosis – tested on Mycobacterium terrae), viral and fungal infections (candidiasis and dermatomycosis)	0.5	30	Immersion
Rigid and flexible endoscopes	Bacterial (except tuberculosis), viral and fungal infections (candidiasis)	0.5	15	Immersion
	Bacterial (including tuberculosis), viral and fungal infections (candidiasis)	0.5	30	

3.6. The disinfection of hard-to-reach small-area surfaces indoors, pieces of furniture, external surfaces of machines, appliances, equipment is performed in line with the guidelines presented in Table 3 by wiping them with a rag saturated with **0.1%** agent water-alcohol solution (in case of bacterial infections except tuberculosis and fungal infections) or with **0.5%** agent water-alcohol solution (in case of bacterial infections, including tuberculosis and fungal infections) at the application rate of 100 ml/m² of the surface. The cleaning is executed one time only. Washing the working solution off the surfaces after the disinfection is not necessary. In case of a viral infection, the surfaces are cleaned twice with **0.5%** agent water-alcohol solution with a 15 minutes' interval between the two disinfection periods.

The maximum allowed area for cleaning cannot exceed 1/10 of the gross floor area.

It is not recommended to apply agent water-alcohol solutions to surfaces covered with lacquer or low-quality paint, as well as to those made of acrylic glass or other materials susceptible to the effect of alcohol. It is recommended to test the agent on a small, hidden surface area before using. Medical transport for contagious patients is disinfected in accordance with the disinfection mode for the relevant infection. Medical transport is disinfected regularly in line with the guidelines presented in Table 3.

Disinfection guidelines for surfaces of various materials using **DEZIN agent water-alcohol solution**

Table 3.

Disinfection objects	Infection aetiology	Working solution concentration by AI (Active Ingredient), %	Disinfection time, min.	Disinfection method
Small-area surfaces indoors, in medical transport, pieces of furniture, appliances, medical equipment	Bacterial (except tuberculosis) and fungal infections	0.1 0.5	30 15	Wiping
	Bacterial (including tuberculosis – tested on <i>Mycobacterium terrae</i>) and fungal infections	0.5	30	
	Viral infections	0.5	30*	Wiping

* wiping twice with a 15 minutes' interval

4. APPLICATION OF DEZIN AGENT WATER SOLUTIONS

4.1 The agent working water solution (0.2% active ingredient) is used for both preventive and local (current and terminal) disinfection of items mentioned in paragraph 1.4. of this Instruction for epidemiological indications.

4.2 The disinfection is performed by wiping. The disinfection of surfaces by wiping them with 0.2% agent water solution (exposure time 60 minutes) in medical and preventive treatment facilities can be performed in the presence of patients without respiratory protective equipment but with hand skin protection.

4.3. The disinfection of indoor surfaces (floor, walls, doors etc.), hard furniture, external surfaces of machines and appliances is executed by wiping them with cloths or rugs saturated with 0.2% agent water solution at the application rate of 150ml/ m² of the treated surface. At the end of the disinfection waiting period, the working solution residuals can be removed from the surface with a wet rug if necessary.

4.4. Sanitary appliances (baths, sinks, lavatory bowls) are disinfected twice with 0.2% agent water solution by wiping with scrubbing and toilet brushes at the application rate of 150ml/m² of the surface. At the end of the disinfection, the surface is rinsed with running water.

5. SAFETY MEASURES

5.1. Apply only as intended for external use.

5.2. Individuals under the age of 18 and individuals with hypersensitivity to chemicals are not allowed to work with the agent.

5.3. Avoid contact with eyes!

5.4. Do not apply to injuries and mucous membranes.

5.5. Do not apply water-alcohol solutions to surfaces susceptible to the effect of alcohols.

5.6. Disinfect the surfaces of medical appliances with the agent solutions using rubber gloves as hand protection.

5.7. Disinfection with water and water-alcohol solutions can be performed in the presence of patients.

5.8. It is forbidden to eat while working with the agent.

5.9. Store separately from medicinal drugs out of reach of children.

5.10. Do not use after the expiration date.

5.11. Water-alcohol solutions are highly flammable! Do not smoke! Avoid contact with open fire and working heating devices.

6. FIRST AID MEASURES

6.1. In case the agent or its solutions come into contact with the eyes, rinse the eyes immediately with running water for 10-15 minutes. Then instill 1-2 drops of 30% sulfacyl-sodium solution. Consult a doctor if necessary.

6.2. In case the agent comes in contact with injuries or damaged skin, rinse immediately with a big amount of water.

6.3. In case the agent or its solutions are ingested, drink several glasses of water with an adsorbing agent (10-15 crushed activated carbon tablets). Do not induce vomiting! Consult a doctor.

7. PACKING, TRANSPORTATION AND STORAGE

7.1. **DEZIN** agent is produced in polymeric containers (bottles and canisters) with a capacity of 0.5 dm³, 1.0 dm³ and 5.0 dm³, in barrels with a capacity up to 200.0 dm³.

7.2. The agent is transported by all means of transport in line with the applicable shipping rules for each means of transport. Handling marks: «Top», «Keep away from direct sunlight».

7.3. In emergency conditions, in case a big amount of the agent has been accidentally spilled, use personal protective equipment (a gown, boots, rubber or polyethylene gloves, universal respirators type RPG-67 (gas protection) or type RU-60M (dust and gas protection) with a filter type A or an industrial respirator). The agent spill must be covered with soil and sand and collected in lidded containers for further disposal. After the cleanup, the contaminated area must be rinsed with a big amount of water.

7.4. Prevent the ingress of undiluted agent into waste/surface or ground waters and drainage systems. Dilute with a big amount of water.

7.5. Packaged agent is stored in dry storage facilities separately from medicinal drugs and foodstuffs, away from sunlight, at a temperature from 0°C to plus 25 °C.