STATE SANITARY AND EPIDEMIOLOGICAL SERVICE OF UKRAINE

MANUAL
Use of Chlorantoin for Disinfection of Facilities and Pre-sterilisation Cleansing of Medical Devices

Kyiv – 2013

Developed by Academician L.I. Medved Research Centre for Preventive Toxicology, Food and Chemical Safety, Ministry of Health of Ukraine, with participation of SPC Farmacos Limited Liability Company (Ukraine).

This Manual is intended for staff of healthcare institutions, sanitary and epidemiologic stations, and disinfection stations, other institutions and organisations or economic operators applying disinfection pre-sterilisation cleansing procedures.

Sanitary and epidemiologic organisations and institutions may reproduce this Manual in such quantity as may be necessary.

Manual on Use of Chlorantoin for Disinfection of Facilities and Pre-sterilisation Cleansing of Medical Devices dd. June 05, 2009 (No. 50-2009) shall be deemed invalid.

.

APPROVED
By Chief Sanitary Officer of Ukraine
A.M. Ponomarenko
- signature -
December 26, 2013
No. *326-2013*
Seal:
State Sanitary and Epidemiological Service of Ukraine
Identification number 37508109

MANUAL
on Use of Chlorantoin for Disinfection of Facilities and Pre-sterilisation Cleansing of Medical Devices

1. GENERAL PROVISIONS

1.1 Product name: Chlorantoin as per Technical Specifications TU U 22902465.004-95 as amended.

1.2 Manufacturer: SPC Farmacos LLC (Ukraine)

1.3 Composition, contents of active ingredients and excipients, % wt: 1,3-dichlor-5,5-dimethyl hidantoin (dichlorantin) – 21.5 to 23,5 (active ingredient); 5.5-dimethyl hidantoin – 12.5 to 16.5; dispersant – 9.0 to 12.5; anionic surfactants – 3.2 to 5.0; corrosion inhibitor up to 10.0; filler up to 100.0. Mass fraction of chlorine is not less than 14.1%.

1.4 Pharmaceutical form, physical and chemical properties: white to yellowish loose powder with moderate odour of chlorine. May contain lumps crushable when pressed. Water content does not exceed 0.3% by mass fraction.

Chlorantoin aqueous solutions are transparent, colourless, with mild chlorine odour, do not damage items made of metal (such as stainless steel, chrome-nickel steel, aluminium, etc.), glass, rubber, polymer and composite materials, wood, tile, porcelain, faience, surfaces of medical devices and pre-painted, galvanized and coated equipment, do not fix protein and fat contamination on surfaces of medical devices, well-washed, and leave no stain. The product is incompatible with cationic surfactants, single and polyhydric alcohols. Compatible with soaps and anionic surfactants. Non-inflammable, non-explosive.

1.5 Intended use: Chlorantoin is intended for:

- Routine and final disinfection of facilities at health care institutions, childcare institutions and points of intestinal and airborne infections of bacterial (including tuberculosis), fungal (candidosis, dermatomycosis, mycelial fungus), viral (including influenza, parainfluenza, viral hepatitis, HIV, poliomyelitis, rotavirus infections) origin and particularly dangerous and zoonotic infections (plague, cholera, anthrax, etc.)
- Pre-sterilisation cleansing and combination of disinfection and pre-sterilisation cleansing of medical items made of corrosion-resistant metal, glass, rubber, polymer and composite materials
- Disinfection of single-use medical devices and used dressings before disposal
- Preventive disinfection and routine and overall cleaning at different healthcare facilities (surgical, therapeutic, urological, renal, ophthalmology, obstetrics, gynaecology, children, TB, infections, physical therapy, pathological and other departments, dental clinics, polyclinics, outpatient clinics, medical aid points, blood banking institutions, clinical, biochemical, bacteriological, serological and other specialized diagnostic laboratories, donor centres, ER stations and vehicles, donor centres, blood transfusion centres, healthcare units and sanitary units, etc.) and pharmacies

- Preventive disinfection and routine and overall cleansing at various diagnostic and testing laboratories
- Preventive disinfection and routine and overall cleansing at recreational institutions (health centres, health and recreation centres, rest homes, boarding houses, etc.)
- Preventive disinfection and routine and overall cleansing at preschool childcare institutions, educational and cultural institutions
- Preventive disinfection and routine and overall cleansing at restaurants and trading facilities
- Preventive disinfection and routine and overall cleansing at sports and recreational institutions
- Preventive disinfection and routine and overall cleansing at social institutions and organisations, prison and custodian facilities
- Preventive disinfection and routine and overall cleansing at communal facilities (hotels, campsites, hostels, hairdressing salons, beauty clinics and salons, tanning salons, laundry, baths, saunas, public toilets, etc.)
- Preventive disinfection and routine and overall cleansing at water supply and sewerage system facilities
- Preventive disinfection and routine and overall cleansing at rolling stock and facilities for passenger transportation (including by rail, air, water, road and underground transport) and vehicles for transportation of food products and raw materials
- Preventive disinfection and routine and overall cleansing in households and epidemiologically important facilities in other production and servicing sectors where disinfection measures are required under applicable sanitary, hygiene and antiepidemic regulations and standards, norms and guidelines
- Sanitary treatment (washing and disinfection) of facilities at companies of perfumes and cosmetic product manufacturing, pharmaceutical industry and microbiology
- Sanitary treatment (washing and disinfection) of facilities of food and processing industry and agricultural business

1.6 Specific biological properties of the product: Chlorantoin demonstrates bactericidal (including antituberculocide), virucide (against pathogens causing poliomyelitis, any type of influenza, parainfluenza, coronavirus, respiratory syncytial infections, rotavirus, adenovirus infections, SARS, hepatitis, HIV, viral gastroenteritis, etc.) sporicidal and fungicidal (including pathogens causing candidosis, dermatomycosis, mycelial fungus) properties. Chlorantoin working solutions homogenized sputum and other excrements, has wetting, emulsifying and cleaning properties, effectively removes mechanical, protein, fat contamination, traces of blood, excrements and medicines from external surfaces, internal channels and cavities of medical devices.

1.7 Product toxicity and safety: Chlorantoin, as required by GOST 12.1.007, belongs to moderately hazardous substances (hazard category 3) in case of ingestion and inhalation to low-hazardous substances in case of contact with the skin (hazard category 4). In case of inhalation as vapours, Chlorantoin is a low-hazardous substance in terms of volatile grade. In a dry state and concentrated solutions, Chlorantoin cause ocular irritation and irritation of the upper respiratory tract. When used in the recommended concentrations for washing and disinfection, the product does not cause skin or ocular irritation. The product has no skin-resorptive, sensitizing, carcinogenic, mutagenic or embryotoxic action (based on the active ingredient).

2. PREPARATION OF WORKING SOLUTIONS

2.1 Methods and conditions for preparation of working solutions: prepare Chlorantoin working solutions in a labelled container made of any material (except for galvanised iron) by dissolving the product in water and mixing for 1 to 2 min. To prepare working solutions, use drinking water. To make 0.5 to 2.5% working solutions, prepare suspension of the product first using a small quantity of water and make up to the volume required. Use of hot water at (60±5) °C to prepare 0.5 to 2.5% solutions is allowed to speed up dissolution in water.

2.2 Calculations for preparation of working solutions: to prepare Chlorantoin working solutions in the concentration required, follow calculations presented in Table 1 below.

Table 1: Calculations for preparation of Chlorantoin working solutions

Concentration, % (based on the product)	1 dm³ of solution		10 dm³ of solution	
	Chlorantoin, g	Volume of water, cm³	Chlorantoin, g	Volume of water, cm³
0.1	1.0	999.0	10.0	9,990.0
0.2	2.0	998.0	20.0	9,980.0
0.3	3.0	997.0	30.0	9,970.0
0.5	5.0	995.0	50.0	9,950.0
1.0	10.0	990.0	100.0	9,900.0
2.5	25.0	975.0	250.0	9,750.0

2.3 Shelf life and storage conditions for the working solution: prepare Chlorantoin working solutions directly before use. Any unused working solution may be stored for 3 days in a container tightly closed with a lid. Unused Chlorantoin working solution is for pre-sterilisation cleansing of medical devices, routine and overall cleaning for 14 days after preparation. Use Chlorantoin working solutions one time for the purposes of disinfection.

3. METHODS OF USE FOR DISINFECTION

3.1 Where to use: use Chlorantoin to disinfect and wash the following items:

- Medical devices (including endoscopes and instruments thereto) made of corrosion-resistant metal, glass, rubber based on silicone or natural rubber, polymer and composite materials
- Medical and other appliances, systems, equipment with plated, lacquer or paint, polymer and combined coating, and those made of glass and rubber
- Patient care items (bedpans, ice bags, heating pads, etc.) and personal care items (combs, sponges, etc.)
- Excrements (urine, faeces, sputum, etc.)
- Linen
- Glassware (household, kitchen, pharmacy, laboratory)
- Containers and reservoirs for drinking water
- Toys
- Surfaces in rooms (floors, walls, doors, window frames and glass, window sills, etc.), furnishings (hard and soft furniture, carpets)
- Equipment and facilities at pharmacies
- Equipment, facilities and containers at food processing units at healthcare and preschool childcare institutions
- Sanitary and technical equipment
- Medical waste (including single-use items made of various materials, dressings, cotton and gauze swabs, gauze pads etc.) before disposal
- Transport facilities
- Cleansing tools
- Containers for waste and litter collection, accumulation and storage
- Technological equipment, facilities, product pipelines, tools, containers used by companies operating in the pharmaceutical, microbiological, perfumery and food processing industries
- Hairdressing, manicure and beauty tools
- Ventilation and air conditioning systems

3.2 Methods for disinfection of certain items with the product: disinfect items by spraying, wiping, soaking, immersing, by volumetric method and by filling in the native powder in accordance with regimens described in Tables 2 to 7 below.

3.2.1 Disinfect medical devices made of corrosion-resistant metal, glass, rubber, polymer and composite materials by immersing into the working solution with appropriate concentration. Make sure the layer above the working solution over immersed medical devices is at least 1 cm thick. Disinfect detachable items with openings and channels (such as syringes) unassembled. Fill in channels and cavities with the working solution using with a continuous-action syringe or an electric suction machine. Keep the container with medical devices soaked in the working solution tightly closed with a lid. After disinfection, rinse medical devices with running drinking water and rinse with distilled water. Rinse channels and cavities of medical devices by injecting running drinking water using a continuous-action syringe or an electric suction machine.

For medical devices or their parts, which do not come in direct contact with a patient, wipe items with a cloth (tissue) soaked with the working solution twice (15 min apart) subject to further exposure for appropriate period of time. After disinfection, rinse medical devices with running water for 3 min. Rinse channels and cavities of medical devices by injecting water using a continuous-action syringe or an electric suction machine.

3.2.2 Immerse Linen (undergarments, Linen, mattress covers, linen bags, etc.) one by one into the working solution based on the formula: 4 L/kg of dry sheets (or 5 L/kg of dry sheets to prevent cholera). Keep the container with medical devices soaked in the working solution tightly closed with a lid. After disinfection, wash and rinse Linen and undergarments.

3.2.3 Make sure tableware is free from leftovers (food, biological materials, excrements, culture media, reagents, etc.) and immerse fully in the working solution. Use working solution at the rate of 2 L/set (a cup, a saucer, a deep and shallow plate, a tea spoon, a table spoon, a fork, and a knife). Fill in laboratory glassware (flasks, cylinders, test tubes, pipettes etc.) with the working solution. Keep the container with glassware soaked in the working solution tightly closed with a lid. After disinfection, wash glassware in water using a bottle brush or a brush and rinse twice (preferably in warm water at (45 ± 5) °C).

3.2.4 Immerse toys fully in the working solution (make sure toys do not come to the surface). After exposure, wash toys in water twice until the chlorine odour completely disappears. Wipe large toys with a cloth soaked with the working solution. Clean soft toys with a brush soaked with the working solution. After disinfection, rinse toys with running water until the chlorine odour disappears.

3.2.5 Wipe surfaces in rooms (floors, walls, doors, window frames etc.) and furnishings with a cloth soaked with the working solution (100 mL/m^2 of surface area) or spray onto surfaces using a special device (consumption rate for disinfection of surfaces in rooms by spraying depends on the type of device used and is described in technical documents to such device). After treatment of surfaces with working solution, allow to expose as required and ventilate the room for 15 min.

3.2.6 Spray the working solution onto surfaces of sanitary and technical equipment or wipe surfaces of sanitary and technical equipment twice (15 min apart) with a cloth or a brush soaked with the working solution. Use 100 mL of working solution per m^2 of surface area for disinfection of sanitary and technical equipment by wiping. When sanitary and technical equipment is disinfected by spraying, refer to documents accompanying special equipment used for spraying for the consumption rate of the working solution. Surfaces of sanitary and technical equipment may be disinfected by cleansing with powder product applied on a brush or cloth. Upon application of the working solution or native product onto surfaces of sanitary and technical equipment, allow to expose as required and rinse sanitary and technical equipment with running water until chlorine odour disappears.

3.2.7 Wipe medical appliances, devices, and equipment with lacquered, painted, plated, polymer and combined coating, and those made of glass and rubbers twice (15 min apart) with a cloth soaked with the working solution and allow to expose as required. Wipe those parts of medical appliances, devices, and equipment in contact with the skin with pads soaked with drinking water.

3.2.8 Remove leftovers of raw materials, semi-finished or finished goods mechanically from working (internal) surfaces of small containers of technological equipment used by pharmacies or companies operating in the pharmaceutical and microbiological industries when such facilities are not equipped with spraying devices, fill in with the working solution (volumetric method of disinfection) and allow to expose as required. After exposure, drain the working solution, rinse items with water for 3 min to remove residues of Chlorantoin.

3.2.9 Remove leftovers of raw materials, semi-finished or finished goods from technological

containers used by pharmacies or companies operating in the pharmaceutical and microbiological industries equipped with spraying devices with water under pressure, 6-8 kg*sec/cm^2 (0.6 to 0.8 MPa) for 30 min., apply the working solution onto surfaces of containers using spraying devices and allow to expose as required. Rinse with cold water under pressure until residues of Chlorantoin are completely removed.

3.2.10 Disinfect mixers used by pharmacies or companies operating in the pharmaceutical and microbiological industries by filling in the internal volume for one third with the working solution when a mixer runs. Switch on a mixer 2 to 5 times for 3 to 5 min. during the exposure time. Switch off a mixer and discard the spent working solution, rinse internal surfaces with water for 3 min. until residues of Chlorantoin are completely removed, allow to air dry.

3.2.11 Disinfect patient care items by spraying, immersing into the working solution or wiping with a cloth soaked with the working solution. After disinfection, rinse patient care items with running water until chlorine odour is completely removed.

3.2.12 Immerse cleansing items into the working solution. After disinfection, rinse items with running water until chlorine odour is completely removed and allow to air dry.

3.2.13 Add the working solution to excrements (blood, serum, sputum, urine, faeces, vomit, etc.), wash water after patient cleaning and washings at 2:1 (working solution: excrements). Keep a container tightly closed with a lid for the period of disinfection.

Excrements may be disinfected by covering with the native powder of Chlorantoin (Make sure there is no patient in a room where items are disinfected by covering with the native powder).

3.2.14 Immerse medical waste (bandages, cotton and gauze tampons, pads, single-use Linen, disposable medical products, etc.) into the working solution in a labelled container. Keep the container tightly closed with a lid for the period of disinfection. Dispose of medical waste after disinfection.

3.2.15 For overall and routine cleaning in rooms, use wiping or spraying. For overall cleaning, remove furniture and items from walls. Ventilate rooms after cleaning.

3.2.16 For disinfection of items with Chlorantoin working solution, follow regimens described in Tables 2 to 7.

For preventive disinfection of items listed in Section 1.5, follow regimens described in Table 2.

3.3. Method of use of Chlorantoin for pre-sterilisation cleansing of medical items: use Chlorantoin working solution for manual or mechanised pre-sterilisation cleansing of medical devices made of corrosion-resistant metal, glass, rubber, polymer and composite materials (except for flexible and rigid endoscopes) after disinfection. Make sure detachable items are disassembled before pre-sterilisation cleansing.

Use the working solution at room temperature or at initial temperature at (45±5) °C for pre-sterilisation cleansing of medical devices.

3.3.1 For manual pre-sterilisation cleansing of medical devices with the working solution, follow the steps below:

- Rinse devices with running water for (0.5±0.1) min.
- Soak devices in 0.2% Chlorantoin solution for (15.0± 1.0) min. Fill in internal channels and cavities of devices with the working solution using a continuous-action syringe or an electric suction machine. Attach needles (one by one) to a syringe filled with the working solution, allow the solution to pass through needles and immerse in the working solution. Soak devices in the working solution in a container tightly closed with a lid. Do not maintain the temperature of the solution during soaking and washing.
- Wash each item, including syringes, in the working solution using a bottle brush or cotton-gauze swab for (0.5±0.1) min. Wash internal channels and cavities of other items by injecting the working solution through such items using a continuous-action syringe or an electric suction machine. Attach needles (one by one) to a syringe filled with the working solution and allow the solution to pass through needles.
- Rinse with running water for 3 min. Rinse internal channels and cavities of devices by injecting running water through such channels and cavities using a continuous-action syringe or an electric suction machine. Attach needles (one by one) to a syringe filled with running water and allow running water to pass through needles.

- Rinse with distilled water for (0.5±0.1) min. Rinse internal channels and cavities of devices by injecting distilled water through such channels and cavities using a continuous-action syringe or an electric suction machine. Attach needles (one by one) to a syringe filled with distilled water and allow distilled water to pass through needles.
- Dry heat-resistant items with hot air at (85±5) °C until moisture is completely removed.

3.3.2. For mechanised cleansing of medical devices with the working solution by jetting, rotary, or bushing methods (brushing may not be used for rubber items) or by ultrasound method

For mechanised cleansing methods, refer to the manual attached to the relevant equipment.

For mechanised cleansing of medical devices with the working solution, follow the steps below:

- Rinse devices with running water for (0.5±0.1) min.
- Mechanically clean using the solution (by rotary method with 0.2% working solution; by jet and brushing method or in combination with ultrasound cleansing with 0.3% working solution).
- Rinse with running water for 3 min.
- Rinse with distilled water for (0.5±0.1) min.
- Dry heat-resistant items with hot air at (85±5) °C until moisture is completely removed.

3.3.3. Disinfection and pre-sterilisation cleansing of medical devices with Chlorantoin working solution may be combined. When disinfection is combined with pre-sterilisation cleansing of medical devices, follow disinfection regimens for relevant infections as described in Tables 2 to 5 below. Use working solution in a concentration no less than 0.2%.

When disinfection and pre-sterilisation cleansing of medical devices are combined, follow the steps below to prepare for sterilisation:

- Immerse items into the working solution with the concentration appropriate for disinfection and allow to expose as required for disinfection. Disassemble detachable items before immersion into the working solution. Fill in internal channels and cavities of items with the working solution using a continuous-action syringe or an electric suction machine. Attach needles (one by one) to a syringe filled with the working solution, allow the solution to pass through needles and immerse in the working solution. Keep a container with items soaked in the working solution tightly closed with a lid. Do not maintain the temperature of the solution during soaking. When the working solution is used in concentration of more than 0.2%, room temperature may be used.
- Wash each item in this working solution using a bottle brush or cotton-gauze swab for (0.5±0.1) min after exposure as required for disinfection. Wash internal channels and cavities of items by injecting the working solution through such items using a continuous-action syringe or an electric suction machine. Attach needles (one by one) to a syringe filled with the working solution and allow the solution to pass through needles.
- Rinse with running water for 3 min. Rinse internal channels and cavities of devices by injecting running water through such channels and cavities using a continuous-action syringe or an electric suction machine. Attach needles (one by one) to a syringe filled with drinking water and allow running water to pass through needles.
- Rinse with distilled water for (0.5±0.1) min. Rinse internal channels and cavities of devices by injecting distilled water through such channels and cavities using a continuous-action syringe or an electric suction machine. Attach needles (one by one) to a syringe filled with distilled water and allow distilled water to pass through needles.
- Dry heat-resistant items with hot air at (85±5) °C until moisture is completely removed.

3.3.4. Chlorantoin working solutions may be used many times for disinfection or pre-sterilisation cleansing of medical devices during the shelf life of the solution provided there is no visual sign of contamination and the mass fraction of the active ingredient in the solution remains the same. When there is a visual sign of contamination (such as sediment, flakes, turbidity, colour change, etc.) and the mass fraction of the active ingredient is lower, the solution should be replaced by fresh one.

Whenever Chlorantoin working solutions are reused, use special testing strips to control whether Chlorantoin working solutions are suitable for use.

4 PRODUCT WARNINGS AND PRECAUTIONS

4.1 Necessary personal equipment for protection of skin, respiratory system and eyes when the product is used. Prepare and use Chlorantoin working solutions by spraying using personal equipment for protection of skin, respiratory system and eyes (such as a coat, a hat, and a rubberised apron, rubber gloves, special footwear, goggles type PO-2, PO-3 or single screen, and a particulate respirator).

4.2 General warnings and precautions when the product is used. Persons under the age of 18 years, pregnant or breast-feeding women or those with hypersensitivity to the product or any of its components may not handle Chlorantoin. Persons with skin lesions such as scratches, wounds and irritation on open parts of the body which may be exposed to the disinfecting product or its working solutions may not handle the product for a while. Do not eat or smoke during disinfection. Once the operations are over, wash your face and hands with soap and water. Take off and wash clothes contaminated with the product before next use.

4.3 Warnings and precautions for preparation of working solutions. Any staff preparing working solutions should be provided with personal equipment to protect skin, respiratory system and eyes (such as a coat, a hat, and a rubberised apron, rubber gloves, special footwear, goggles type PO-2, PO-3 or single screen, and a particulate respirator).

4.4 Warnings and precautions when the product is used for cleansing of certain items. When 0.1 to 0.2% Chlorantoin solutions are used for spraying and wiping, the active ingredient (dichlorantin) is non-detectable in the breathing air in rooms within the sensitivity limits of the method used. The contents of the hydrolysate the active ingredient (free chlorine) in the air do not exceed exposure limit for atmospheric air in inhabited locations. Surfaces in rooms, furniture, equipment and facilities may be disinfected with 0.1 to 0.2% Chlorantoin solutions by wiping and items may be disinfected with 0.1 to 1.0% Chlorantoin solutions by immersing in a container with a tightly closed lid in the presence of patients and other persons not directly involved in the disinfection procedures.

For preventive disinfection at preschool childcare facilities by wiping or spraying with Chlorantoin solutions, make sure children are absent during the disinfection procedure and ventilate the rooms for 30 min.

4.5 Product disposal. Discard Chlorantoin working solutions (up to 1.0%) into the sewerage system. Dilute working solutions of higher concentration with water before discarding into sewerage system.

Return batches of Chlorantoin which are expired or found defective due to violation of storage conditions to the manufacturer for further processing.

5. SIGNS OF ACUTE POISONING AND FIRST AID FOR POISONING

5.1 Signs of acute poisoning. Signs of ocular irritation and irritation of the upper respiratory tract include lacrimation, conjunctival oedema, hyperaemia, throat tickle and cough.

5.2 First aid for acute (respiratory) poisoning. In the event of inhalation, make sure a suffered has access to fresh air or is in a well-ventilated room, keep the suffered at rest and warm, and loosen tight clothing. Warm milk is recommended.

5.3 First aid for contact with eyes. In case of accidental contact with eyes, rinse eyes with running water for 10 to 15 min. In the event of ocular irritation, drop 30% sulfacyl sodium (albucid) solution into eyes and seek medical advice.

5.4 First aid for contact with skin. Rinse the exposed skin with running water. In case of contact with working clothing, take off the clothing and rinse the exposed skin under the clothing with running cold water.

5.5 First aid for ingestion. Drink several glasses of cold water and induce vomiting. Milk is recommended.

5.6 Neutralisation of product. Neutralise product residues at facilities used by human with 1.0% sodium thiosulfate.

6. PACKAGING, TRANSPORTATION AND STORAGE

6.1 Product packaging. Chlorantoin (net weight: 5 kg to 20 kg) is packed in three-layer paper bags ПМ or ВМ with polyethylene inserts, convolute drums with polyethylene inserts, and plywood drums with polyethylene inserts. The product (net weight: 0.25 to 2.0 kg) is packed in polymer packaging, plastic containers for medical products and food supplements. The product may also be packaged in paper sachets with internal PE laminated layer.

6.2 Product transportation conditions. Chlorantoin may be transported by road or rail in the original packaging in accordance with rules applicable for hazardous cargo transportation by road or rail.

6.3 Shelf life and storage conditions. Store Chlorantoin in the original packing in covered, dry, well-ventilated area with restricted access at 5°C to 30°C at least 1 m from heating devices. Avoid direct sunlight. Pile boxes and bags containing the product on wooden pallets or polymer pallets. Make sure the height of a pile does not increase 2.5 m. Guaranteed shelf life is 3 years upon the date of manufacture.

7. PRODUCT QUALITY CONTROLS

7.1 List of parameters to be defined. Mass fraction of active chlorine

7.2 Methods of determination:

7.2.1 Determination of mass fraction of active chlorine in Chlorantoin

7.2.1.1 Measurement tools, reagents and auxiliary materials.

Laboratory balance, accuracy grade 2 with the highest weight limit of 200 g, unit value: 0.0001 as required by DSTU 7270.

Measuring cylinders 1-50-2 as required by DSTU ISO 4787.

Flask KH-1-250-19/26 TC as required by GOST 25336.

Glasses B-1-10, B-1-50 as required by GOST 25336.

Pipettes 1-1-1-2, 2-2-15 as required by GOST 29227.

Burette 1-1-2-25-0.1 as required by GOST 29251.

Water, laboratory grade, as required by DSTU ISO 3696.

Potassium iodide as required by GOST 4232, allow to stay, freshly prepared 10% solution (by mass fraction).

Glacial acetic acid as required by GOST 61, C.P., 20% solution (by mass fraction).

Soluble starch as required by GOST 10163, 0.5% solution (by mass fraction).

Sodium thiosulfate solution as required by GOST 27068, c($Na_2S_2O_3 \cdot 5\ H_2O$)=0.1 mole/dm^3 (0.1 N).

7.2.1.2 Preparation to testing

7.2.1.2.1 Preparation of standard sodium thiosulfate solution.

Prepare sodium thiosulfate solution c($Na_2S_2O_3 \cdot 5\ H_2O$)=0.1 mole/dm^3 (0.1 N) precisely as required by DSTU 7259 or from fixanal.

7.2.2. Testing procedure

Weigh the quantity of the product (0.2 g) to the fourth decimal, transfer into a 250 cm^3 conical flask, dissolve in 50 cm^3 of distilled water, add 15 cm^3 of acetic acid, and then add 15 cm^3 of potassium iodide solution. Close a flask with a stopper soaked with potassium iodide solution, mix thoroughly and allow to stay in a dark place for 3 min. Titrate released iodine with sodium thiosulfate solution until straw-yellow staining appears, add 2 cm^3 of starch solution and continue titration until blue colour disappears. Make a control test in parallel.

7.2.3. Interpretation of test results

7.2.3.1. Calculate the mass fraction of active chlorine in the product (X_1) as a percentage using the formula below:

$$X_1 = \frac{(V-V_1) \cdot 0{,}003545 \cdot 100}{m}, \qquad [1]$$

where: V – volume of sodium thiosulfate solution, precise concentration $c(Na_2S_2O_3 \cdot 5\ H_2O)$ = =0.1 mole/dm³ used to titrate the selected weighed quantity of the product, cm^3;
V_1 – volume of sodium thiosulfate solution, precise concentration $c(Na_2S_2O_3 \cdot 5\ H_2O)$ =0.1 mole/dm³ used to titrate the control sample, cm^3;
m – mass of weighed quantity of the product taken for testing, g;
0.003545 – mass of active chlorine corresponding to 1 cm^3 of sodium thiosulfate solution, concentration $c(Na_2S_2O_3 \cdot 5\ H_2O)$=0.1 mole/dm³, g;

7.2.3.2. Take the arithmetic mean of the results of two parallel tests as the test result provided the allowable differences between tests do not exceed 0.3%, confidence level P = 0.95.

Table 2: Regimes for disinfection of facilities with Chlorantoin solutions to prevent bacterial intestinal and airborne infections (except for tuberculosis) and infections with parenteral transmission of viral pathogens (hepatitis, AIDS, etc.)

Object of disinfection	Concentration, % (based on product)	Exposure time, min	Disinfection method
1	2	3	4
Surfaces in rooms (floors, walls, doors, window frames, window sills), solid furniture etc.	0.1 0.2 0.2* 0.5*	60 30 60* 45*	Spraying or wiping
Tableware free from leftovers (including single-use tableware)	0.1	30	Immersion
Tableware with leftovers (including single-use tableware)	0.2	60	Immersion
Laboratory glassware	0.1 0.2* 0.5*	30 90* 45*	Immersion
Wipes, brushes for washing tableware and dining table surfaces	0.2	60	Immersion
Linen free from excrements	0.1	30	Soaking
Linen dirty with excrements	0.2	60	Soaking
Toys (rubber, plastic, metal, composite materials)	0.1 0.2	60 30	Immersion or wiping
Patient care items	0.2	60	Immersion, wiping or spraying
Medical devices made of rubber, corrosion-resistant metals, plastics, glass and composite materials	0.1 0.2 0.2* 0.5*	60 30 60* 30*	Immersion or wiping

Table 2 (continued)

1	2	3	4
Medical and other appliances, systems, equipment with lacquer or paint, plated, polymer and combined coating, and those made of rubber and glass	0.1 0.2 0.2* 0.5*	60 30 60* 30*	Wiping
Refrigerators, cooling chambers, refrigerating units (internal surfaces) and other technological equipment	0.1	60	Wiping or spraying
Containers for drinking water	0.1 0.2	60 30	Filling in or wiping
Sanitary and technical equipment (baths, wash-basins, water closets etc.)	0.2	60	Spraying, wiping or cleansing with dry product using a brush
Glassware dirty with excrements (bedpans etc.)	0.2	90	Immersion
Cleaning tools	0.2	60	Immersion
Excrements (faeces, urine, blood and blood derivatives, sputum, vomit, water after washing a patient, washings), biological waste	0.2	90	Fill with solution at a ratio of 2:1 (solution volume to volume of excrements) or fill with dry product
Medical textile waste (tampons, pads, dressing, single-use lines, special clothing etc.)	0.2	60	Fill with solution at a ratio of 2:1 (solution volume to volume of waste)
Vehicles	0.1 0.2	60 30	Wiping or spraying

Note: *Regime of disinfection of items dirty with blood.

Table 3: Regimes for disinfection of facilities with Chlorantoin solutions to prevent viral airborne infections (any type of influenza, parainfluenza, adenoviral, respiratory syncytial, rhinovirus and other infections)

Object of disinfection	Concentration, % (based on product)	Exposure time, min	Disinfection method
1	2	3	4
Medical devices made of corrosion-resistant metal, glass, rubber, polymer and composite materials	0.1 0.2	60 30	Immersion or wiping
Surfaces in rooms (floors, walls, doors, window frames, window sills), solid furniture etc.	0.1 0.2	60 30	Spraying or wiping
Tableware free from leftovers	0.1	30	Immersion
Tableware with leftovers	0.1	60	Immersion
Laboratory glassware	0.1	60	Immersion
Linen free from excrements	0.1	30	Soaking
Linen dirty with excrements	0.1	60	Soaking

Toys	0.1	30	Immersion
Patient care items	0.1	60	Immersion, wiping or spraying
Medical devices and appliances with lacquer or paint, plated, polymer and combined coating, and devices made of rubber and glass	0.1	60	Wiping
Refrigerators, cooling chambers, refrigerating units (internal surfaces) and other technological equipment	0.1	60	Wiping or spraying
Sanitary and technical equipment	0.1	60	Spraying or wiping
Cleaning items	0.1	60	Immersion
Excrements (faeces, urine, blood and blood derivatives, sputum, vomit, water after washing a patient, washings), biological waste	0.1	60	Fill with solution at a ratio of 2:1 (solution volume to volume of excrements) or fill with dry product
Vehicles	0.1	60	Spraying or wiping

Table 4: Regimes for disinfection of facilities with Chlorantoin solutions to prevent viral intestinal infections (poliomyelitis, rotavirus, enterovirus etc.)

Object of disinfection	Concentration, % (based on product)	Exposure time, min	Disinfection method
1	2	3	4
Surfaces in rooms (floors, walls, doors), solid furniture etc.	0.1 0.2	60 30	Spraying or wiping
Tableware free from leftovers	0.2 0.5	60 45	Immersion
Tableware dirty with leftovers	0.2 0.5	60 45	Immersion
Laboratory glassware	0.2 0.5	90 60	Immersion
Wipes, brushes for washing tableware and dining table surfaces	0.2 0.5	90 60	Immersion
Linen free from excrements	0.2 0.5	60 45	Soaking
Linen dirty with excrements	0.2 0.5	90 60	Soaking
Toys	0.2	60	Immersion
Patient care items (heating pads, lining circles, lining cloth etc.)	0.2 0.5	60 45	Immersion, wiping or spraying
Medical devices made of rubber, corrosion-resistant metal, plastics, glass, and composite materials	0.2 0.5	60 40	Immersion or wiping
Rubber gloves	0.2 0.5	120 60	Immersion
Laboratory table surfaces at clinical, biochemical and other diagnostic laboratories	0.2 0.5	90 60	Wiping or spraying
Medical devices and appliances with lacquer or paint, plated, polymer and combined coating, and devices made of rubber and glass	0.2 0.5	60 45	Wiping
Glassware dirty with excrements (bedpans, chambers etc.)	0,2 0.5	90 60	Immersion
Sanitary and technical equipment	0.2 0.5	90 60	Spraying or wiping
Cleaning items	0.2 0.5	90 60	Immersion
Excrements (faeces, urine, blood and blood derivatives, sputum, vomit, water after washing a patient, washings), biological waste	0.2	120	Fill with solution at a ratio of 2:1 (solution volume to volume of excrements) or fill with dry product
Vehicles	0.2 0.5	60 45	Spraying or wiping

Table 5: Regimes for disinfection of facilities with Chlorantoin solutions to prevent tuberculosis

Object of disinfection	Concentration, % (based on product)	Exposure time, min	Disinfection method
1	2	3	4
Surfaces in rooms (floors, walls, doors, window frames), solid furniture	0.2 0.5	120 30	Spraying or wiping
Soft furniture, carpets, small household items, soft toys	0.2 0.5	120 30	Brushing or wiping with a cloth soaked with the solution
Tableware free from leftovers, bottles from medicines including single-use items	0.2	120	Immersion
Tableware dirty with leftovers including single-use items	0.3 0.5 1.0	120 60 30	Immersion
Food leftovers	2,5	360	Fill with solution at a ratio of 2:1 (solution volume to volume of food leftovers)
Laboratory glassware	0.5 0.7 1.0	120 60 30	Immersion
Containers for drinking water	0.2 0.5	120 30	Wiping or filling
Linen (bed sheets, underwear, cover for furniture, gauze respirators etc.) free from excrements	0.2 0.5	120 30	Soaking
Linen (bed sheets, underwear, cover for furniture, gauze respirators etc.) dirty with excrements	0.5 0.7 1.0	90 60 20	Soaking
Handkerchiefs, inserts for spittoons, cases for spittoons	0.5 0.7 1.0	120 60 30	Soaking
Toys (rubber, plastic, metal, wooden, etc.)	0.3 0.5 0.7	120 60 30	Immersion
Patient care items	0.5 0.7 1.0	120 60 30	Immersion, wiping or spraying
Medical devices made of rubber, corrosion-resistant metal, plastics, glass and composite materials (including single-use items)	0.2 1.0	120 30	Immersion or wiping

Table 5 (continued)

1	2	3	4
Medical devices, appliances and equipment with lacquer or paint, plated, polymer and combined coating, and devices made of rubber and glass	0.2 0.5	120 30	Wiping
Glassware dirty with excrements	0.5 0.7 1.0	120 60 30	Immersion
Sanitary and technical equipment	0.2 0.5	120 30	Spraying or wiping
Cleaning items	0.5 0.7 1.0	360 180 120	Immersion
Sputum in spittoons	2.5	180	Immersion
Sputum	2.5	360	Fill with solution at a ratio of 2:1 (solution volume to volume of sputum)
Spittoons free from sputum	2.5	120	Immersion
Excrements (faeces, urine, blood and blood derivatives, sputum, vomit, water after washing a patient, washings), biological waste	2.5	360	Fill with solution at a ratio of 2:1 (solution volume to volume of excrements) or fill with dry product
Vehicles	0.5 0.7 1.0	120 60 30	Spraying or wiping

Table 6: Regimes for disinfection of facilities with Chlorantoin solutions to prevent fungal infections (dermatomycosis, candidosis, contamination with mould fungi etc.)

Object of disinfection	Concentration, % (based on product)	Exposure time, min	Disinfection method
Surfaces in rooms (floors, walls, doors, windows)	1.0	90	Spraying or wiping
Tableware free from leftovers (including single-use items)	1.0*	30	Immersion
Tableware dirty with leftovers (including single-use items)	1.0*	30	Immersion
Laboratory glassware	1.0	90	Immersion
Linen (underwear, bed sheets) and other textile items	1.0	60	Soaking
Toys (rubber, plastic, metal, wooden, etc.)	1.0* 1.0	30 90	Immersion
Combs, scissors, brushes, barrettes, etc.	1.0	90	Immersion
Medical devices made of rubber, corrosion-resistant metal, plastics, glass and composite materials (including single-use items)	1.0	120	Immersion or wiping
Rubber carpets	1.0	90	Immersion, wiping or spraying
Sanitary and technical equipment (baths, wash-basins, water closets etc.)	1.0	120	Filling (a batch) with the solution, spraying wiping or cleansing with dry product
Cleaning items	1.0	90	Immersion

Note: *Disinfection regimens for candidiasis.

Table 7: Regimes for disinfection of facilities with Chlorantoin solutions at points of highly infectious diseases

Object of disinfection	Concentration, % (based on product)	Exposure time, min		Disinfection method
		Plaque	Cholera	
Surfaces in rooms (floors, walls, doors, windows), solid furniture etc.	1.0	-	60	Spraying or wiping
	0.2	-	30	
	0.7	60	-	
Porous or plastered surfaces	0.2	-	60	
Medical devices, appliances and equipment with lacquer or paint, plated, polymer and combined coating, and devices made of rubber and glass	0.1	-	60	Wiping
	0.2	-	30	
	0.7	60	-	
Laboratory glassware	1.0	-	60	Immersion
	0.2	-	30	
	0.7	60	-	
Dirty linen (underwear, bed sheets), protective clothing and other textile items	0.5	-	60	Soaking
	1.5	60	-	
Patient care items	0.5	-	60	Immersion, wiping or spraying
	0.7	60	-	
Medical devices made of rubber, corrosion-resistant metals, plastics, glass and composite materials (including single-use items)	0.7	60	-	Immersion or wiping
Sanitary and technical equipment (baths, wash-basins, water closets etc.)	0.2	-	60	Spraying or wiping
	0.7	60	-	
Cleaning items	0.2	-	60	Immersion
	1.5	60	-	
Excrements (faeces, urine, blood and blood derivatives, sputum, vomit, water after washing a patient, washings), biological waste	1.5	-	240	Fill with solution at a ratio of 2:1 (solution volume to volume of excrements) or fill with dry product
	2.5	360	-	
Vehicles	0.1	-	60	Spraying or wiping
	0.2	-	30	
	0.7	60	-	