

New Disinfectant GELACIDE C and Possibilities of its Use

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Introduction

When providing the health care to injured persons in the field, one of the basic preconditions of success is effective disinfecting, resp. treatment by antiseptic agent, of not only the injury itself and its environment but also protection of the medical workers. Especially at the possibility of using biological means, it is necessary to have in the equipment effective remedies, which are able to clean the relevant spot from pathogenic microorganisms or in an appropriate way eliminate their action. This concerns also using the elements of military health care for humanitarian missions and missions centred on settlement of consequences of natural disasters. In the area of operation there practically doesn't exist any infrastructure, there must be replaced a large number of human and animal remains and there is a great danger of spreading epidemics. Development of these means and their inclusion in outfit of the field medical service is thus a necessary and permanent process.

At the Military Epidemiological Department (KVE) of the Military Medical Research and Training Institute of Jan Evangelista Purkyně (VLVDÚ JEP) in Hradec Králové there was in the 70s of the last century developed a new disinfectant based on organically fixed iodine with use of exchanger as a carrier. In this time there practically started to be broader used so-called iodophors, i.e. remedies based on polymers with organically fixed iodine. These remedies show high disinfecting effect and, in comparison with the original low-molecular iodine remedies with inorganically fixed iodine (iodine tincture, Lugol's solution), they don't colour so much and they are more durable. The original iodine remedies were noted for high poignancy and danger of allergy occurrence.

At the iodophors active on surface, where iodine is fixed on micelle basis, these undesirable features are considerably reduced and it's also possible to use them in different forms as solutions, salves, creams, gels and similar.

The preparative developed at KVE was used in form of powder, solution and gel and in 80s it had been clinically tested at several departments of the Central Military Hospital (ÚVN) in Prague, in the Military Hospital (VN) in Brno and in then VÚHEM (Military Institute of Sanitation and Epidemiology) in Prague. Results of these tests, which were comparatively very successful, will be described in further text.

However, since the date of the first clinical testing of the preparative a lot of time has passed. Nevertheless, its author, Ing. Drahoš SOKOL, CSc., who had been working at KVE for a long time, didn't use the relatively favourable situation of that time and he didn't finish development into the final form of the remedy. Since then the Czech Republic became a member of EU, before that it had legalized the GMP principles (Good Manufacturing Practice) and above all there had been accepted the strict rules for registration of remedies. Performance of all necessary tests substantially increased, as for their number, as well as their price.

The described preparative is thus not a registered medical product, but a medical means of the class IIa, according to the Act n. 336/2004 Coll., on technical requirements for medical means, which was issued in accordance with the Directive of Council n. 93/42/EHS and according to which there is required just “check of accordance”, i.e. marking by “CE”. The means of the class IIa belongs to the most invasive medical means, which get in contact with injured skin, and are determined to treat the instant environment of wounds. There is required only safety of preparative according to the Act n. 231/2004 Coll., on contents of safety list for dangerous chemical substance and preparative. Beside the check of accordance it is necessary for medical means of this kind to perform the test for human skin tolerance. The preparative GELACIDE C gained all the three above-mentioned certificates in 2006, resp. 2005 in case of skin tolerance.

The preparative is now made by the firm Ecoton spol. s r.o., Plhovské nám. 1101, 547 01 Náchod.

In the following text there will be stated some facts concerning the preparative, above all the test results. This article has above all informative character. In case of interest you can address directly the producer of this product.

Characteristic of the active substance, product description and directions for use

The preparative GLACIDE C represents a certain form of iodophor. Macromolecular carrier is made of ion exchanger of annex type, to which there is fixed an anion of trichloriodic acid. Active compound is here iodic chloride (ICl_3), which has been known for longer time as an effective disinfecting and antiseptic agent. The above stated anion is released from the carrier and it act on membranes of microorganisms – when they are impaired, pathogenic organisms die. This disinfecting principle isn't based on halide action of albumins (blood, sputum, sweat etc.), therefore its effectiveness isn't reduced by presence of body fluids.

The preparative itself contains ca 3 % of active substance in 100 ml of salve basis in form of semi-solid gel paste. The salve basic consists of a mixture of glycerol, polyethylene glycol, polyvinyl alcohol, purified water and other substances.

The product is determined for external use, namely for skin disinfecting and as a protective (biological gloves) preventing the penetration of infective agent. Its efficiency is not reduced even at bleeding injuries. It isn't toxic nor irritable. When using as a protective, apply on the cleaned hand skin ca 2 cm (1-2 g) of the preparative from the tube, thoroughly spread this quantity on the entire surface of your hands by rubbing and let it dry for 5 minutes. This should be disinfected also wounds or operation field. The preparative can be used also under the safety gloves, which can positively influence the impacts of injury in case of their damage. At moistening of the protective film there can appear increased tackiness of the surface, which disappears when dried. The protective film preserves its efficiency minimally for 3 hours and it resists also washing by water for 30 seconds. After finishing the activity it can be easily removed by using soap, subsequently it is suitable to treat the skin by a regeneration hydrating cream.

When penetrating in eyes it acts irritably, therefore it is necessary to rinse them with a stream of potable water and to see a doctor.

The preparative causes browning of golden and silver jewellery and it infracts the nail-varnish. This colouring of things is reversible and it can be removed for example by warming or simmering in water. The preparative isn't toxic nor dangerous for the environment.

Minimum durability of the preparative was determined as 5 years, storing temperature shouldn't surpass 50°C.

Performed tests on efficiency and health tolerance

Since finalization of developing the active substance it's efficiency has been repeatedly tested, both in laboratory conditions and at the clinics, in order to gain appropriate certificates also at the sites accredited for this purpose.

Beside the tests, which were performed before finalization of development at KVE, there were performed following tests:

1980 – 1985

The active substance in form of 1 % solution with dikonit (sodium dichloroisocyanurate with 55 % of active chlorine) with the title POLICID C, resp. POLICID I, was tested in some departments of ÚVN Prague and in form of 2 % salve, where the salve basics consisted of synderman (industrially produced salve basics) in VN Brno. The gestor of these clinical tests was then VÚHEM Prague. Both remedies were altogether used at more than 235 ill persons, involved with different ulcerous and inflammatory illnesses at following departments.

At the dermatology department the remedies were used in case of contaminated skin defects, pyoderma, skin mycosis and ulcerous balanitis. There was confirmed marked antiseptic and healing effect at 38 of in total 42 patients.

A positive effect was achieved also in the cases, where the actual treatment by antibiotics and antiseptic agents failed. They were not observed any side effects, especially irrigative effects or skin allergies.

At the department of facial and jaw surgery the remedies were used to rinse fistulas, chronic ulcer focuses, soft and hard tissues and ulcer focuses after extraction. At all 50 patients, where the remedy had been applied, there were accelerated repairing processes leading to healing of defects. At 11 cases there succeeded also shorter healing of simple affections by herpes simplex.

At the ORL department there occurred fast healing at 48 patients with complicated inflammation of alvearium, where the usually applied therapy with use of above all peracetic acid failed, within 3 days, at four of them within 1 week and only at five per cent healing lasted more than 1 week.

At surgery departments the remedies were used for rinsing and compressing of ulcer fistulas, for treatment of projectile wounds and large deep injuries of soft tissues by complicated inflammation. In altogether 24 cases there occurred fast clearing of wound surface and sub sequential healing of defects. Positive effect was observed even in case of anaerobic infections (*Clostridia*, *Bacteriodes*). The salve proved good also at primary treatment of facial skin burnings.

At the gynaecology department positive effect was showed at vaginal fluorines, where the remedies were successfully used at 26 patients in form of lavage.

To assess this period of clinical testing in total, its therapeutic effect was indisputable, in comparison with the actual treatment methods (local, antiseptic agents, antibiotics and chemotherapy), above all as for reduced time of healing, even in the cases, where the actual therapies were not successful, whereas there were not observed any side effects.

1996 – 1997

Testing of the preparative, this time with the title POLYCIDGEL, was performed at KVE Military Medical Academy of Jan Evangelista Purkyně (VLA JEP) in Hradec Králové.

The active substance was again iodic chloride on annex carrier, but this time in form of yellow-brown liquid with higher thickness. It was recommended to apply it raw on hands, where it should dry in 3 minutes and form a protective film, which should guarantee at least three hours of efficiency. The preparative was tested on artificially contaminated hands of persons on trial for bactericidal and antiviral efficiency. The preparative was further tested for disinfecting hands also under the surgical gloves and separately for two other strains, *Pseudomonas aeruginosa* and *Candida albicans*, at exposing for 5 and 180 minutes.

For testing there was used the method of finger prints with standard testing microbial strains, which are usually used by the National referential laboratory for disinfecting and sterilisation SZÚ Prague (Paříková, 2002). The testing strains were *Staphylococcus aureus* (representative of G⁺ bacteria), *Escherichia coli* (representative of G⁻ bacteria), *Escherichia coli bacteriophage* (representative of viruses) and beside the basic methodology also *Pseudomonas aeruginosa* and *Candida albicans*.

To detect the **bactericidal efficiency** of the preparative, the tips of the fingers of the persons on trial were contaminated by one drop of 16hour broth culture with average number of germs 5×10^6 CFU/ml (CFU=colony forming units). The hands were after rubbing and drying moistened by water and treated by raw preparative with the exposing time of 5 minutes. At further experiment the fingers of persons on trial were after 3 hours of exposing printed on solid agar plate, each hand separately. Each person on trial made the check prints the same way before the preparative started working. All agar plates were then incubated in thermostat at 37°C. There was assessed number of colonies on both plates (check plates and experimental plates) per one hand.

Antiviral efficiency of the preparative was detected at the model virus *Escherichia coli bacteriophage* on the host *Escherichia coli* by the plaque method. /2/. For testing there was used the method of preparative effect on artificially contaminated hands of the persons on trial in a similar way like at detecting the bactericidal efficiency – tips of one finger of each hand of the persons on trial were contaminated by one drop of virus suspension with titre 10^6 PFU/ml (PFU = plaque forming unit). After drying of the contaminating suspension the hands were treated by the raw preparative with the exposing time of 5 minutes. The tips of the fingers were printed in the similar way on the solid soil with hosting *Escherichia coli*. There was assessed number of plaques per one hand before and after treatment by the preparative POLICIDGEL.

Testing of the **hand disinfectant** was performed according to methodology recommended by the supplier in directions for use. The hands were washed by soap, which was perfectly rinsed by running water. After drying both hands were covered by 2 ml of the raw preparative, which was thoroughly spread on the entire surface and after 5 minutes, when the preparative dried in form of a protective film, it was rinsed by warm water and when dried there were made prints on appropriate media. In the same way there were then repeatedly made prints after 3 hours, whereby the persons on trial were occupied by other manual activity during this time.

Assessing of the **disinfecting efficiency under the sterile surgical gloves** was performed in the following way. The hands of the persons on trial were washed by warm water and liquid soap and dried in a stream of warm air. After taking the check prints on the masopepton agar plate the left hand of the person on trial n. 1 was provided by a sterile surgical glove without use of the tested preparative, while the right hand was slightly moistened by water, on it there was spread ca 0,5 g of the preparative and after drying by warm air it was also provided by a sterile surgical glove. After 3 hours of common laboratory work both gloves were taken off and the fingers were printed on agar plate as usual. At the check persons n. 2 and 3 there was after taking the check prints and after slight moistening spread on both hands 1 g of the preparative and after drying by warm air there were applied

this time non-sterile surgical gloves. There were taken finger prints, in the same way like at the person on trial n. 1.

Detailed results of all stated tests have been stated in the survey /3/. In the conclusions of this work it is stated that the raw preparative POLICIDGEL on base of iodic chloride showed, according to the performed tests, an excellent antimicrobial efficiency at 5 minutes long exposing, and at the same time favourable remanent activity after three hours long exposing. Perfect disinfecting effect was proved under the sterile, as well as non-sterile surgical gloves. For its outstanding features this preparative was recommended as a suitable remedy – so called “biological gloves” for the areas with less exposed contamination.

2005

The bactericidal and fungicidal efficiency of the preparative GELACIDE C – this time already gel – was assessed in form of laboratory expertise of the National referential laboratory for disinfecting and sterilization, Epidemiological and Microbiological Centre SZÚ in Prague. There were performed similar tests like in the stated expertise /3/ on more persons on trial and they in principle confirmed the results stated in the conclusion of the work.

At disinfecting of the artificially and naturally contaminated hand skin there was active the assessed preparative as bactericide at use of 1,5 ml on a moistened hand, active for 3 minutes or until its drying. The preparative has residual effects and for the time of 90 minutes of common work there were not released any microorganisms from inner skin layers. After three hours from applying there were appearing separate microbe colonies. The efficiency wasn't neutralized when washed by soap solution for 30 seconds. In total, the number of microorganisms was reduced by 5 log orders.

The fungicidal efficiency (leaven microscopic fungi) was assessed roughly assessed only at contamination of hands in surgical gloves. The efficiency was satisfactory, similar like at bacteria. The preparative showed on the treated hands in surgical gloves residual effects for the time of 1 hour. In a thin layer on the contaminated hands of the persons on trial it inactivates the model virus on the hands at exposing for 3 minutes (there have been proved just separate PFU), at exposing for 1 hour there succeeds complete inactivation of PFU of the model virus. Results of the tested samples from products of different age are comparable, which means that during storage the disinfecting efficiency doesn't drop.

2006

In the Centre of Sanitary Laboratories, Medical Institute with the seat in Hradec Králové, there were performed tests on bactericidal efficiency of the textile, impregnated by the preparative POLICID C against the generally incident microbes. For testing there were used similar stems like at the precedent tests. i.e. *Escherichia coli*, *Enterococcus faecalis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Candida albicans*.

The above stated stems were newly multiplied and inoculated to nutrient agar. For testing there was used suspension of stems in the physiological solution with turbidity intensity 0,5 grade according to MC Farland turbidity scale. This suspension was diluted in the ratio 1:1000 by the physiological solution (at the stem *Candida albicans* 1:100) and applied to Petrie plate with the diameter 9 cm with the life agar in it. For each bacterial stem there were used 6 plates and to each of them there was applied 0,2 ml of microbe suspension. The testing textile was cut in blanks of the parameters 2x2,5 cm, which were being printed on the prepared Petrie plates.

On each stem there was tested a textile impregnated by the tested preparative in six different exposing times: immediate print, print for the time of one, two, three, four and five minutes.

All the plates were then incubated at 37°C and the following day there was made deduction of colonies. Detailed results of this deduction are stated in the study. /8/

The study conclusions declare 100 % efficiency of the textiles impregnated by the preparative POLICID C as early as after 3 minutes of exposing. Seldom presence of just a few colonies at shorter exposing times doesn't have to be ascribed to shorter activity but, for instance, to less perfect textile adhesion to surface of the nutrient agar on the Petrie plate.

The last testing of the preparative, this time again GELACIDE C, was the "compulsory" testing of the skin tolerance. The testing was performed by the laboratory of the Health and Life Conditions Centre SZÚ in Prague, according to SOP n.1/13 on Cosmetic Product Test Guidelines for Assessment of Human Skin Compatibility. For the testing there were used 20 persons on trial with the definitive conclusion that in the testing conditions there wasn't proved any potential of skin irritability at the given product.

Possibility of Practical Use

In relation to its high disinfecting efficiency, which has been proved by all the above-mentioned tests, it is possible to use this preparative as a common disinfecting preparative. Because of the film creating features of the salve basis, i.e. creating of s called "biological gloves", it is possible to use it widely at medical solution of different critical situations, namely in the places with occurrence of greater number of corps, especially at the lack of unobjectionable water for execution of general sanitary measurements.

It could be further used in practice of the field medical facilities, namely also within the pre-operative preparation of the medical staff, at manipulation with contagiously ill persons etc. It could be also used in pacific and field veterinary practice, at preparation of antiseptic kinds of bandage material and in different types of first-aid kits.

There were also proved effect at the treatment of skin mycoses, warts and herpes, though still not founded by larger tests. The preparative can also kill leeches and it acts positively on the majority of minor injuries caused by insect.

Which is also important is the fact that the efficient quantity of the stated preparative in comparison with similar, but also liquid products, is substantially smaller, which could at larger utilization lead to reduction of the stored and transferred material.

Conclusion

The preparative described in this article isn't a registered remedy, but a medical means. In spite of that, with regard to its high disinfecting efficiency and protective features it's possible to recommend it for wide use not only in the pacific but above all in the field human and veterinary medicine. It could be used very efficiently for instance in the practice of rescue units and organs at liquidation of the disaster impacts of different kinds. In these situations it's especially not possible to avoid contact with the human and animal corps and the preparative could thus protect the intervening staff also in the case of unprotected hands, and also at failure of protective gloves. The text of this article was centred on the descriptive level and overall assessment of the product efficiency. In case of possible interest further information can be received at the product producer at the address state in the introduction to this article or at this e-mail address: ecoton@ecoton.cz

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