

**National Health Institute**  
Epidemiology and Microbiology Centre  
National Reference Laboratory for Disinfection and Sterilization  
Škrobárova Str. 48  
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## Germicidal and Virucidal Efficacy of GELACIDE C (Gel)

Laboratory Expertise No. 41 399 68/2005

### **Germicidal and Fungicidal\* Efficacy of GELACIDE C (Gel)** (\*Microscopic Yeast-like Fungi)

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Technical Cooperation: Zuzana LÁNSKÁ, Lenka KUBÍKOVÁ

### **Virucidal Efficacy of GELACIDE C (Gel)** Jelena PAŘÍKOVÁ, DSc.

Technical Cooperation: Marcela Maháčková

|  |   |                  |
|--|---|------------------|
| NRL for Disinfection and Sterilization | V. Melicherčíková, M.D., PhD –<br>Head of Laboratory  | <i>Signature</i> |
| Epidemiology and Microbiology Centre   | B. Kříž, M.D., PhD –<br>Head of Centre  |                  |
|  | Stamp:<br>EMC National Reference Laboratory<br>for Disinfection and Sterilization<br>NATIONAL HEALTH INSTITUTE,<br>PRAGUE |                  |

## **Product Characterization**

**The Expertise ordered by (Customer):** ECOTON s.r.o.  
Plhovské náměstí 1101, 547 01 NÁCHOD

**Producer:** ECOTON, s.r.o., Náchod, Czech Republic

**Product Description** (based on the Producer's data):

### **GELACIDE C – Gel:**

A hand disinfectant with residual effect. The product is germicidal, fungicidal and virucidal. Applied on wet hands (1.5 to 2 ml) and let dry it creates a flexible and mechanically resistant film. The film keeps its antiseptic effects for 3 hours. It contains anioactive resins (Icl3), glycerin, polyethyleneglycol, Sloviol R, Neoaquasorb, a regenerating cream distributed in the Czech Republic under the name of "*Indulona*", Dikonit, purified water.

### **Documents Submitted:**

- A design of the respective Czech label
- The respective Material Safety Data Sheet in the Czech language
- Producer's documentation
- Laboratory Expertise (VLA JEP) by M. Hartmanová: Evaluation of the *Polycid Gel* product for hand disinfection (1996-97). According to the customer's information, the formulas of *Polycid Gel* and Gelacide C – Gel are identical.

Subject matter of this Expertise was interpretation of the Product antiseptic efficacy results through laboratory experiments.

### **Interpretation of the Laboratory Test Results:**

Three minutes after application of 1.5 ml., the Product shows germicidal, fungicidal and virucidal effect. The residual effect lasts for 1.5 to 3 hours if normal laboratory work is performed and for 1 hour under surgical gloves. The Product is easily washable with soap and water. After work, the hands should be treated with a moisturizing cream. Due to the consistency of the Product, laboratory suspension experiments could not be carried out.

The Product has not been tested or evaluated for its corrosivity, toxicity, irritability or labour safety. The Product should not come into contact with gold jewellery or nail polish. The yellowish film on the hands runs and may stain other things if touched. The hands on which the Product has been applied have a typical smell of the chemicals used in the Product.

As this is a new domestic product, field practical experiments to check its antiseptic efficacy and properties should be carried out. It is recommendable to use the Product if there is a need for long-term microbial cleanliness of the hands, nevertheless the Product cannot replace protective gloves.

No proof or evidence of the Product effect on pathologic prions have been submitted.

This study applies to the samples submitted only and the conclusions arising herefrom can only be applied to other products of the same kind if their formula and properties are identical with those examined by our laboratory.

Pursuant to Par. 80, Clause 1, Section g) and Par. 77, Clause 1, Section a) of Act 258/2000 Sb. of Public Health Protection and of Amendment of Some Related Acts the Decision is not to be issued by the Chief Health Officer of the Czech Republic starting from July 1, 2002. This Expert Opinion serves a source document to evaluate the disinfectant pursuant to the Biocides Act (120/2002 Sb.)

## **Determination of the Germicidal, Fungicidal\* and Virucidal Efficacy of the Product** (\*Microscopic Yeast-like Fungi)

To determine the microbicidal efficiency of a disinfectant, the following method is used:

Experiments on the hands of experimental persons simulate practical conditions. The experimental persons' fingertips or wrists are artificially contaminated with bouillon culture (0.1 ml) of *St. aureus* or *E. coli*, or with *E. coli* bacteriophage phi X 174 when determining the virucidal efficiency of the Product. After drying, the hands are treated with the Product following the method recommended by the producer (1.5 ml / 3 minutes, 1.5 hour / 3 hours). Then the fingertips or wrists are printed on an agar medium plate. The growth of the microbes and its intensity are then compared with check fingerprints. By washing the fingers or wrists in a soap solution the action of chlorohexidine or of KAS is neutralized. (SOP-NRL/DS 08-01, 09-01, 10-01, 11-01).

### **The Results**

See Laboratory Test Report No. 165/2005 attached hereto.

Applied on the artificially and naturally contaminated and wet skin on the hands (1.5 ml), the Product showed bactericidal effects after three minutes after application (or after getting dry). The Product further showed its residual efficacy, for the period of 1.5 hour, no microbes were released from the inner layers of the skin during routine work. Three hours after application, individual colonies of microbes started to appear. The action was not neutralized by washing the hands in a soap solution for 30 seconds. The microbe count decreased by 5 log. orders.

The fungicidal efficacy on microscopic yeast-like fungi was roughly evaluated only when the hands were contaminated in surgical gloves. The microbe cannot be put directly on the skin. The efficacy was satisfactory, similar to that with germs. The results are not given in the table.

Applied on the hands in surgical gloves (1.5 ml after 3 minutes or until the hands became dry), the Product showed residual efficacy for 1 hour.

Put in a thin layer on the experimental persons' contaminated hands, the Product inactivates the model virus on the hands in 3 minutes (only individual PFU's were proved). After one-hour exposure there was 100 per cent inactivation of the PFU's of the model virus. The sample for testing the virucidal effectiveness was fresh and delivered just before testing.

Put in a thin layer on the experimental persons' contaminated hands, the Product inactivates the model virus on the hands in 3 minutes (only individual PFU's were proved). After one-hour exposure there was 100 per cent inactivation of the PFU's of the model virus. The sample for testing the virucidal effectiveness was older, delivered some time before

testing. The virucidal efficacy of both the samples (the new one and the older one) were comparable which means that the effectiveness does not change with time.

**Literature:**

1. Standard Methods of Evaluating Antiseptic Efficacy of Chemical Substances  
AHM, Annex No. 1, 1985, Pages 1 through 25.
2. V. Melicherčková: "Sterilization and Disinfection in Health Service"  
Grada Publishing, 1998
3. Company Documentation
4. O. Bydžovská: "Screening Method for Viral Disinfection Evaluation through the  $\Phi$ X  
174 Bacteriophage"  
AHM, No. 2, Year 14, Pages 51 through 54, SZÚ, Prague 1984
5. List of Disinfectants, mph – Verlag GmbH, Wiesbaden, Germany, 2002 – xero.

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A Laboratory accredited by ČIA under Ref. Number No. 1206.4 according to ČSN EN ISO/IEC 17025

## Laboratory Test Report No. 165/2005

**Customer (Orderer):**

Customer's Name and Address: ECOTON s.r.o., Plhovské nám. 1101, 547 01 NÁCHOD

Contact Person (name, phone): Václav KUBÍČEK, Phone: 491 451508

**Material Examined:**

Product Name: GELACIDE C – Gel

Effective Substance(s): Anioactive resins (Icl3), glycerin, polyethyleneglycol, Sloviol R, Neoaquasorb, a regenerating cream distributed in the Czech Republic under the name of "Indulona", "Dikonit", purified water.

Characterization & Manner of Application: A germicidal, fungicidal and virucidal hand disinfectant with residual effect. Put on the hands, it creates a flexible and mechanically resistant film on the skin.

Manner of application: An amount of 1.5 to 2 ml of GELACIDE C is to be put on wet hands, thoroughly rubbed into the skin of the hands and let dry. The Product then keeps its antiseptic effectiveness for three hours.

Producer: ECOTON s.r.o., Plhovské nám. 1101, 547 01 NÁCHOD, Czech Republic

Packing: A plastic bottle

Number of Original Intact Bottles Provided: 1

Total Amount of the Product Provided: 200 ml

Charge Number or Marking: "Laboratory Sample"

The Respective Tests Began on: February 4, 2005

The Test Methods Used: (9 – SOP NRL/DS)

Date of Sampling: February 2, 2005

Expertise Number: 41 399 68/2005

**Laboratory Tests:**

The Test methods Used: 08 – 01, 09 – 01, 10 – 01, 11 – 01

The Tests Carried Out by: Dr. Melicherčíková, Dr. Paříková, Ing. Urban, Kubíková, Lánská, Macháčková

The Respective Tests Began on: February 4, 2005

The Respective Tests Completed on: February 28, 2005

Test Results: See Tables No. 1 through 4

Conclusion: Applied in the amount of 1.5 ml, the Product has germicidal, fungicidal and virucidal effect. The effect begins three minutes after application and lasts for 1.5 to 3 hours after application. The Product forms a yellowish film on the hands.

Laboratory Declaration: The test results apply to the samples mentioned in the Test Report only and they do not substitute other documents. The Test Report may only be reproduced as a whole after the prior consent of the Testing Laboratory.

Date of Test Report: March 7, 2005

Signature of the Head of the Laboratory: Signed: *V. Melicherčíková, M.D., PhD*,

The Test Report by: Dr. Melicherčíková, *Signature*, Stamp:

EMC National Reference Laboratory  
for Disinfection and Sterilization  
NATIONAL HEALTH INSTITUTE, PRAGUE

The Test Report sent to the Customer on: March 8, 2005

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## Laboratory Test Report No. 165/2005

Table 1

| Hand Disinfection       |           |                      |                |     |         |     |
|-------------------------|-----------|----------------------|----------------|-----|---------|-----|
| <b>SOP-NRL/DS/08/01</b> |           |                      |                |     |         |     |
| Dosage                  | Exposure  | Experimental Persons | Microbe        |     |         |     |
|                         |           |                      | Staph. Aureus  |     | E. Coli |     |
|                         |           |                      | Neutralization |     |         |     |
|                         |           |                      | No             | Yes | No      | Yes |
| Wet Hands<br>1.5 ml     | 3 Minutes |                      | No             | Yes | No      | Yes |
|                         |           | 1                    | -              | -   | -       | -   |
|                         |           | 2                    | -              | 15  | -       | -   |
|                         |           | 3                    | -              | -   | -       | -   |
|                         |           | 4                    | -              | -   | -       | 5   |
|                         |           | 5                    | -              | 1   | -       | -   |
| Check                   | +++       | +++                  | +++            | +++ |         |     |
| Wet Hands<br>1.5 ml     | 3 Hours   |                      | No             | Yes | No      | Yes |
|                         |           | 1                    | 27             | 103 | -       | -   |
|                         |           | 2                    | 20             | 25  | -       | -   |
|                         |           | 3                    | 42             | 38  | -       | 8   |
|                         |           | 4                    | 9              | -   | 3       | -   |
|                         |           | 5                    | 13             | 6   | -       | -   |
| Check                   | +++       | +++                  | +++            | +++ |         |     |
| Wet Hands<br>1.5 ml     | 1.5 Hour  |                      | No             | Yes | No      | Yes |
|                         |           | 1                    | 2              | -   | -       | -   |
|                         |           | 2                    | 6              | -   | 4       | 9   |
|                         |           | 3                    | 2              | 1   | 2       | -   |
|                         |           | 4                    | 2              | -   | -       | -   |
|                         |           | 5                    | 1              | 2   | -       | -   |
| Check                   | +++       | +++                  | +++            | +++ |         |     |

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Table 2

| Disinfection of the Skin with Natural Microbial Contamination<br>SOP-NRL/DS/08/01 |                                      |                                  |    |
|---|--------------------------------------|----------------------------------|----|
| Experimental Person   | Microbe Count before<br>Disinfection | Microbe Count after Disinfection |    |
|   |                                      | Neutralization                   |    |
|   |                                      | Yes                              | No |
| 1.5 ml / 3 minutes  | ++                                   | -                                | 13 |
|   | ++                                   | -                                | -  |
| 1.5 ml / 3 hours  | ++                                   | 21                               | +  |
|   | ++                                   | 25                               | +  |
| 1.5 ml / 1.5 hour   | ++                                   | -                                | 60 |
|   | ++                                   | -                                | 65 |

Legend: - no colonies grew on the fingerprints  
+ ++ +++ microbe-growth intensity  
figure = number of colonies on a fingerprint

**Test Result:**

Applied on the artificially and naturally contaminated and wet skin on the hands (1.5 ml), the Product started to show its bactericidal effect three minutes after application. The Product further showed its residual efficacy, for the period of 1.5 hour, no microbes were released from the inner layers of the skin during routine work. Three hours after application, individual colonies of microbes started to appear. The action was not neutralized by washing the hands in a soap solution for 30 seconds. The microbe count decreased by 5 log. orders.

The fungicidal efficacy on microscopic yeast-like fungi was roughly evaluated only when the hands were contaminated in surgical gloves as the microbe cannot be put directly on the skin. The efficacy was satisfactory, similar to that with germs. The results are not given in the table.

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## Laboratory Test Report No. 165/2005

Table 3

| <b>Testing the Virucidal Efficacy of a Hand Disinfectant Using the Method of Disinfected Contaminated Experimental Persons' Fingerprints (Handprints)</b> |   |                     |                      |
|---|---|---------------------|----------------------|
| Virus: <i>E. coli</i> bacteriophage $\phi$ x174   |   |                     |                      |
| Disinfectant: Gelacide C – Gel  |   |                     |                      |
| Dosage (in ml)  | Exposure (in minutes)   | Experimental Person | Efficacy (PFU Count) |
| Hand Disinfection   | Concentrated Disinfectant (Gel) Put on the Hands<br>3-minute Exposure | 13                  | 4                    |
|   |   | 2                   | 1                    |
|   |   | 3                   | 0                    |
|   |   | 4                   | 0.5                  |
|   |   | 5                   | 7                    |
|   |   | CH                  | $10^6$               |
| Hand Disinfection   | Concentrated Disinfectant (Gel) Put on the Hands<br>1-hour Exposure   | 1                   | 0                    |
|   |   | 2                   | 0                    |
|   |   | 3                   | 0                    |
|   |   | 4                   | 0                    |
|   |   | 5                   | 0                    |
|   |   | CH                  | $10^6$               |

**SOP NRL/DS: 09 – 01**

Legend: CH = Check = a print of contaminated uninfected hands  
PFU = Plaque-forming Unit

**Test Result:**

Put in a thin layer on the experimental persons' contaminated hands, the Product inactivates the model virus on the hands in 3 minutes (only individual PFU's were proved). After one-hour exposure there was 100 per cent inactivation of the PFU's of the model virus. The sample for testing the virucidal effectiveness was fresh and delivered just before testing.

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## Laboratory Test Report No. 165/2005

Table 4

| <b>Testing the Virucidal Efficacy of a Hand Disinfectant Using the Method of Disinfected Contaminated Experimental Persons' Fingerprints (Handprints)</b> |   |                     |                      |
|---|---|---------------------|----------------------|
| Virus: <i>E. coli</i> bacteriophage $\phi$ x174   |   |                     |                      |
| Disinfectant: Gelacide C – Gel  |   |                     |                      |
| Dosage (in ml)  | Exposure (in minutes)   | Experimental Person | Efficacy (PFU Count) |
| Hand Disinfection   | Concentrated Disinfectant (Gel) Put on the Hands<br>3-minute Exposure | 1                   | 0                    |
|   |   | 2                   | 0.5                  |
|   |   | 3                   | 0.5                  |
|   |   | 4                   | 0.5                  |
|   |   | 5                   | 2                    |
|   |   | CH                  | $10^6$               |
| Hand Disinfection   | Concentrated Disinfectant (Gel) Put on the Hands<br>1-hour Exposure   | 1                   | 0                    |
|   |   | 2                   | 0                    |
|   |   | 3                   | 0                    |
|   |   | 4                   | 0                    |
|   |   | 5                   | 0                    |
|   |   | CH                  | $10^6$               |

**SOP NRL/DS: 09 – 01**

Legend: CH = Check = a print of contaminated uninfected hands  
PFU = Plaque-forming Unit

**Test Result:**

Put in a thin layer on the experimental persons' contaminated hands, the Product inactivates the model virus on the hands in 3 minutes (only individual PFU's were proved). After one-hour exposure there was 100 per cent inactivation of the PFU's of the model virus. The sample for testing the virucidal effectiveness was older, delivered some time before testing. The virucidal efficacy of both the samples (the new one and the older one) were comparable which means that the effectiveness does not change with time.