Department of Biocidal Products Implementation
Ekolabos sp. z o.o. (Ltd)
Duńska Street 9
54-427 Wrocław

Report No.: **RB/5035/03/2021**

Date issued: 12 March 2021

Virucidal efficacy assessment report

for the product

Cloth - polyester microfiber cleaner containing colloidal silver

according to PN-EN 14476+A2:2019-08 and PN-EN 16615:2015-06 standard,

made for the company

RAYPATH INTERNATIONAL Sp. z o. o. sp.k.

30-199 Kraków, Rząska

Nad Potokiem Street 7a

Poland

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Signed by: Mateusz Latosiński Eng.
Signed by QES

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1. INTRODUCTION

The properties of biocidal preparations, before they are authorised for use, are assessed based on tests carried out in accordance with European standards or other methods accepted by designated national authorities.

The standardisation of testing methods in recent years, through the development of successive European standards on the efficacy of disinfectants and antiseptics, allows a uniform, objective assessment of the antimicrobial effect of these agents and guarantees that the products offered in the market have adequate efficacy.

2. PURPOSE OF THE STUDY

The aim of the study was to assess the biocidal efficacy of the product in relation to Vaccinia virus strain Elstree (ATCC VR-1549).

3. FORMAL BASIS

The assessment of antibacterial efficacy was carried out on the basis of the agreement/order dated 24 March 2021 (agreement No.: AFC/022789/03/21/WRO) concluded between the Contracting Party and the Contractor.

Contracting Party:

RAYPATH INTERNATIONAL Sp. z o. o. sp.k.

30-199 Kraków, Rząska

Nad Potokiem Street 7a

Poland

Contractor:

EKOLABOS sp. z o. o.

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4. LEGAL BASIS

The legal basis for the conducted tests is:

The Act of 9 October 2015 on biocidal products

PN-EN 14476+A2:2019-08 Chemical disinfectants and antiseptics – quantitative suspension method for the evaluation of virucidal effect in the medical area – test method and requirements (phase 2 / step 1)

PN-EN 16615:2015-06 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2)

5. SAMPLE IDENTIFICATION[1]

The tested sample was the biocidal product in the form of a ready to use. The preparation was accepted for testing on 2 March 2021. Sample code assigned by the laboratory: 012/03/03/21.

Product name: Cloth - polyester microfiber cleaner containing colloidal silver

Batch No.: no data

Product reference number: ref. 141, ref. 402/409

Manufacturer:

RAYPATH INTERNATIONAL Sp. z o. o. sp.k.

30-199 Kraków, Rząska

Nad Potokiem Street 7a

Poland

Date of manufacture: no data

Expiry date: no data

Product appearance: cloth - a cleaning cloth made of polyester microfiber, thickness approx. 0.8 mm

Recommended product solvent: N/A

Storage conditions: no data

Active substances present in the product provided by the Contracting Party:

- colloidal silver

[1] Declaration by the Principal

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6. SCOPE OF TASKS PERFORMED

Phase 2, step 1 and step 2 assessment consists in using the dilution and neutralisation method in which the test organism is exposed to the preparation at different concentrations, times and temperatures with the addition of aggravating substances. These methods are to confirm the efficacy of the product in laboratory conditions, similar to the intended use.

6.1 CONDITIONS OF THE TEST PERFORMED

Tests performed on: 03 march 2021 – 09 march 2021

Identification of the microbial strains and cell lines:

Virus strain	Collection catalogue number	Cell line	Collection catalogue number
Vaccinia virus strain Elstree	ATCC VR-1549	Vero	ATCC CCL-81

Incubation for 72h at 37 °C ± 1 °C + 5%CO2

Number of times the test is repeated on the microbe: 1

Test temperature: 20°C ± 1°C

Duration of the product contacting the microbial suspension: 60 s ± 10 s

Interfering substances: beef albumin 0.3g/l

Stability of product mixture with solvent:

No precipitation formed during the test.

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6.2 TESTING METHOD AND VALIDATION

Method used: the test was performed on 4 fields accordingly to PN-EN 16615:2015-06, then enumeration of inactivated virus was done according to PN-EN 14476+A2:2019-08

Counting method: observation of cytopathic effect**,** endpoint titration $TCID_{50}$

Neutraliser used, composition:

- Eagle minimal medium (MEM)

Substrates used:

- Eagle minimal medium (MEM) + 10% FBS - medium used to multiply cell lines,
- Eagle minimal medium (MEM) + 2% FBS - medium used to determine the product's activity, cytotoxicity, susceptibility of tested strains to glutaraldehyde, and to determine the concentration of viral strains (the medium was prepared with 4% FBS concentration, for the final concentration of FBS to be at 2%).

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7. TESTS RESULTS

The results of product testing are presented in tables 1-2.

Table 1. Results of validation tests

Virus under test	N	N_0	N_{v0}	B	C	D_{C0}	D_{Ct}	N_w
Vaccinia virus strain Elstree (ATCC VR-1549)	**N: 8,65**	**7,35**	120,0	120,0	**110,0**	**7,14**	**7,03**	**370,0**

N – initial virus titre used for testing expressed in logarithmic form
N_0 – virus titre introduced on each test surface expressed in logarithmic form
N_{v0} – virus titre introduced on validation surface expressed in logarithmic form
B – virus titre in neutralization contol
C – virus titre in method validation
D_{C0} – virus titre immediately after drying time
N_w – virus titre in water method control
D_{Ct} – virus titre after drying time, plus contact time without the virucidal

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Table 2. Audit results

Test organism	D_{Ct}	Results
Vaccinia virus strain Elstree (ATCC VR-1549)	7,03	10^{-0}:0 10^{-1}:0
		Na: <1,00 **X_{wm}:0**
R=(D_{Ct} – Na)		**R: >6,03**

Na – non-inactivated virus left on test surfaces
R – achieved reduction of the virus titre
X_{wm} – residual non-inactivated virus left on test surfaces

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Specific comments:

Verification of methodology – requirements and limits:

- The titre of virus N used in the test is at least 10^8 (≥8 lg), or is at least high enough to demonstrate R above 4lg,
- Cytotoxicity allows to show the reduction of virus titre >4 lg,
- N_{V0} in between 30 and 160
- B i C are at least equal 0,5xN_{V0},
- D_{C0} i D_{Ct} are between 6,88 a 8,40,
- N_w is on average >10,
- X_{wm} is lower then 50 on active concentrations.

8. CONCLUSIONS

The product tested in accordance with PN-EN 14476+A2:2019-08 and PN-EN 16615:2015-06 standard, during 60 s, in temperature of 20°C, with the presence of interfering substance, shows Virucidal efficacy antiviral effect (reduction ≥4 lg) in relation to:

Vaccinia virus strain Elstree ATCC VR-1549 at 80% concentration

Date issued: 12 March 2021

Report prepared by: Jakub Jałówko, M.Sc

The results were authorised by: Mateusz Latosiński, Eng

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