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

Report No.: **RB/6958/06/22**
Date issued: 21th of June 2022

CONFIDENTIAL

Sporicidal efficacy assessment report

for the product

GLOBACID SF

according to PN-EN 17126:2019-01 standard

made for the company

Goodpoint Chemicals OÜ

Urda tee 3, Jälgimäe, Saku vald, Harjumaa

Estonia 76404

Ekolabos sp. z o.o. (Ltd)
Environmental Research Laboratory
Duńska Street 9, 54-427 Wrocław

biuro@ekolabos.pl
www.ekolabos.pl
phone +48 71 738 20 25

KRS: 0000552492
VAT CODE: 8943061284
REGON: 361267090

Signed by: Mateusz Latosiński Eng.
Signed by QES

CONFIDENTIAL

CONTENTS

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 purpose of the study was to assess the sporicidal efficacy of the product in relation to *Clostridium difficile R027* NCTC 13366 strain.

3. FORMAL BASIS

The assessment of biocidal efficacy was carried out on the basis of the agreement/order dated 11th of January 2022 (agreement No.: 226/01/2022) concluded between the Contracting Party and the Contractor.

Contracting Party:

Goodpoint Chemicals OÜ

Urda tee 3, Jälgimäe, Saku vald, Harjumaa

Estonia 76404

Contractor:

EKOLABOS sp. z o. o.

Environmental Research Laboratory

ul. Duńska 9, 54-427 Wrocław

Poland

4. LEGAL BASIS

The legal basis for the conducted tests is:

The Act of 9 October 2015 on biocidal products

PN-EN 17126:2019-01 Chemical disinfectants and antiseptics – quantitative suspension method for the determination of the sporicidal effect of chemical disinfectants used in the medical sector. According to the standard, the disinfectant has an sporicidal effect on the strain used if the logarithm for bacterial spores reduction obtained in the test is ≥4.

5. SAMPLE IDENTIFICATION[1]

The test sample was the biocidal product, in the form of a product for dilution. The preparation was accepted for testing on 11th of January 2022. Sample code assigned by the laboratory: 2/17/01/22. Product was delivered by the Contracting Party. After the time it was accepted for testing, and before the start of analysys the product was kept according to the storage conditions. Container was not breached until product testing started. Contractor does not bear responsibility for product stability after opening.

Product name: GLOBACID SF

Lot No.: 092023S

Product reference number: no data

Manufacturer:

Goodpoint Chemicals OÜ

Urda tee 3, Jälgimäe, Saku vald, Harjumaa

Estonia 76404

Date of manufacture: 05.2021

Expiry date: 05.2024

Product appearance: clear, transparent liquid.

Recommended product solvent: no data

Storage conditions: room temperature

[1] Declaration by the Principal

Ekolabos sp. z o.o. (Ltd)
Environmental Research Laboratory
Duńska Street 9, 54-427 Wrocław

biuro@ekolabos.pl
www.ekolabos.pl
phone +48 71 738 20 25

KRS: 0000552492
VAT CODE: 8943061284
REGON: 361267090

Active substances present in the product provided by the Contracting Party and their concentrations:

- CAS: 7173-51-5 Didecyldimethylammonium chloride 6%
- CAS: 2372-82-9 N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 5,5%

6. SCOPE OF TASKS PERFORMED

Phase 2, stage 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: 6th of June 2022– 20th of June 2022

Identification of the bacterial strains:

Clostridium difficile R027 NCTC 13366

A suspension of spores and bacteria was prepared from the reference strain and subjected to thermal and enzymatic purification of vegetative forms. The obtained spor suspension after maturation was subjected to glutaral and peracetic acid resistance test according to point 5.4.1.3.3 of PN-EN 17126:2019-01 standard. The resistance test results obtained were within the limits. Immediately before testing the product, the ratio of vegetative forms to spores was checked and it did not exceed 20%.

Incubation for 24 h at 37 °C ± 1 °C under anaerobic conditions

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

Required test temperature: 20 °C ± 1 °C

Duration of the product contacting the bacterial suspension: 40 min ± 5 sec

interfering substances beef albumin 0.3g/l

Ekolabos sp. z o.o. (Ltd)
Environmental Research Laboratory
Duńska Street 9, 54-427 Wrocław

biuro@ekolabos.pl
www.ekolabos.pl
phone +48 71 738 20 25

KRS: 0000552492
VAT CODE: 8943061284
REGON: 361267090

Solvent used during the test:

demineralized water

Stability of the product during the test:

Product stable during the study.

6.2 TESTING METHOD AND VALIDATION

Method used: neutralisation of solutions

Counting method: surface inoculation on plates

Neutraliser used, composition:

Polysorbate 80 – 30 g/l

Sodium thiosulphate – 10 g/l

Lecithin– 3 g/l

The neutraliser used allowed the method to be validated.

Substrate used: Brain heart infusion with cysteine & lysozyme Agar (BHIYT-L), Tryptone Soya Agar (TSA)

Ekolabos sp. z o.o. (Ltd)
Environmental Research Laboratory
Duńska Street 9, 54-427 Wrocław

biuro@ekolabos.pl
www.ekolabos.pl
phone +48 71 738 20 25

KRS: 0000552492
VAT CODE: 8943061284
REGON: 361267090

7. TESTS RESULTS

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

Table 1. Results of validation tests

Test organism	Test bacterial suspension	Bacterial validation Suspension	Validation test	Neutraliser toxicity control	Test using water
	N	**Nv_0**	**A**	**B**	**C**
Clostridium difficile R027 NCTC 13366	10^7: >330 10^8: 38 **N: 7.58**	**Nv_0: 77**	**A: 71**	**B: 73**	**C: 72**

N – log from the number of CFU/ml put in the test suspension
Nv_0 – 1/10th of number of CFU/ml in the validation suspension
A – number of CFU/ml in the mixture to be validated
B – number of CFU/ml in the control mixture for neutraliser toxicity
C – number of CFU/ml in the mixture to be controlled using water and the highest concentration of the active substance

CONFIDENTIAL

Ekolabos sp. z o.o. (Ltd)
Environmental Research Laboratory
Duńska Street 9, 54-427 Wrocław

biuro@ekolabos.pl
www.ekolabos.pl
phone +48 71 738 20 25

KRS: 0000552492
VAT CODE: 8943061284
REGON: 361267090

Signed by: Mateusz Latosiński Eng.
Signed by QES

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

Table 2. Test results

Test organism	N_0	Results for individual concentrations of the product in volumetric % (test conditions: contact time: 40 minutes, temperature: 20°C ± 1°C)		
		5%	4%	0.1%
Clostridium difficile *R027* NCTC 13366	6.58	<14, <14	<14, <14	>330, >330
		Na: <140 Log Na: <2.15	Na: <140 Log Na: <2.15	Na: >3300 Log Na: >3.52
R (N_0 – Log Na)		R: >4.43	R: >4.43	R: <3.06

N_0 – log (N/10);
Na – number of CFU/ml in the test mixture after exposure to the preparation;
R – logarithm bacterial cell reduction obtained during the test

CONFIDENTIAL

Ekolabos sp. z o.o. (Ltd)
Environmental Research Laboratory
Duńska Street 9, 54-427 Wrocław
biuro@ekolabos.pl
www.ekolabos.pl
phone +48 71 738 20 25
KRS: 0000552492
VAT CODE: 8943061284
REGON: 361267090

Signed by: Mateusz Latosiński Eng.
Signed by QES

Specific comments:

Verification of methodology – requirements and limits:

- N is between $1.5x10^7$ CFU/ml and $5x10^7$ CFU/ml ($7.17 \leq \log N \leq 7.70$),
- N_0 is between $1.5x10^6$ CFU/ml and $5x10^6$ CFU/ml ($6.17 \leq \log N_0 \leq 6.70$),
- N_{V0} is between 30 CFU/ml and 160 CFU/ml
- N_V is between $3.0 x10^2$ CFU/ml and $1.6 x10^3$ CFU/ml
- The control of the weighted averages from the successive dilutions used for calculations is between 5.0 and 15.0.
- the average number of bacteria on each plate used for the calculation and obtained from the active concentration test is between 14 and 330
- A, B and C are equal to or greater than $0.5xN_{V0}$
- At least one test concentration of the product must show a reduction log ≥4

and at least one test concentration of the product must show a reduction log <4 in order to demonstrate the biocidal effect of the product.

8. CONCLUSIONS

The product, tested in accordance with PN-EN 17126:2019-01 standard, after contact time of 15min, in the temperature of 20 °C, with the presence of aggravating substance, shows sporicidal effect in relation to:

Clostridium difficile R027 NCTC 13366 **at 2,5%** concentration

The results obtained during all controls and tests met all the requirements of the methodology and were within the limits set.

Date issued: 21th of June 2022

Report prepared by: Agnieszka Pawelec, M.Sc

The results were authorised by: Agnieszka Pawelec, M.Sc

The report was approved by: Mateusz Latosiński, Eng

--- END OF REPORT ---

Ekolabos sp. z o.o. (Ltd)
Environmental Research Laboratory
Duńska Street 9, 54-427 Wrocław

biuro@ekolabos.pl
www.ekolabos.pl
phone +48 71 738 20 25

KRS: 0000552492
VAT CODE: 8943061284
REGON: 361267090

Signed by: Mateusz Latosiński Eng.
Signed by QES