

3rd October 2019
Lex Van Der Heijden
European Registration Office B.V.
Kruisdonk 66, 6222 PH, Maastricht
Pirbright Ref.: ASF0519

Dear Lex Van Der Heijden,

I am pleased to inform you that the product **MS Megades Novo**, effectively inactivated over 2 log₁₀ of African swine fever virus at the dilution of 1:399 (one part disinfectant to three hundred and ninety nine parts of hard water), however, a contact time was unable to be determined. A log reduction could not be determined for dilutions 1:99 (one part disinfectant to ninety nine parts hard water), 1:132 (one part disinfectant to one hundred and thirty two parts hard water) and 1:199 (one part disinfectant to one hundred and ninety nine parts hard water).

Having demonstrated that your product was effective, may I point out that you are not to state or imply that The Pirbright Institute recommends or approves this product for use against African swine fever virus and all correspondence and marketing must clearly state the log reduction provided.

Yours sincerely



3rd OCTOBER 2019

LORRAINE FROST
TECHNICAL MANAGER, DISINFECTANT TESTING
Non-vesicular Disease Reference Laboratory
The Pirbright Institute
GU24 0NF

Lorraine Frost
Technical Manager Disinfectant Testing



This is version 2 of the cover letter due to name change from ERO MN to MS Megades Novo

Test Report

General Test Information

Test Title	Testing the efficacy of disinfectants against African swine fever virus
Tests Conducted by:	Isobel Stokes
Project number:	ASF0519
Sponsor:	Lex Van Der Heijden European Registration Office B.V. Kruisdonk 66, 6222 PH, Maastricht
Test facility	The Pirbright Institute Ash Road, Pirbright, Surrey, GU24 0NF

Test Substance Identity

Test Substance Name:	MS Megades Novo
Lot/Batch(es):	190529-01
Date of manufacture:	29/05/2019
Expiry Date(s):	29/05/2021

Formulation:

Ingredient	Exact percentage of disinfectant ingredients
Gluteraldehyde	14.7%
Benzalkonium chloride	9.8%

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pH of the test substance under test condition:

Dilution Rate	pH
1:99	7.18
1:132	7.28
1:199	7.33
1:399	7.39

Date disinfectant and paperwork received: 18/07/2019

Test Dates

Start Date: 29/08/2019

End Date: 04/09/2019

Objective

The objective of this assay was to determine the effectiveness of disinfectant MS Megades Novo to inactivate ASFV at 1:99, 1:132, 1:199 and 1:399 following BDTL-SOP-3 'Suspension Test for the Disinfectant Efficacy against ASFV'.

Test Materials

Test Organism(s)	Strain	Growth Medium	Cell Line
ASFV	Ba71v	DMEM with 1% antibiotics	VERO

Test Method

Test used: BDTL-SOP-3 Suspension test for the disinfectant efficacy against ASFV

Source of Test Organism

ASFV virus strain Ba71v (VERO cell adapted strain). The strain was passed through VERO cells to produce a VERO cell adapted strain and grown from a stock culture stored at -70°C.

Preparation of Test Control

The test control virus was prepared by mixing 0.1ml of the test organism with 0.9ml of WHO hard water. A reference inactivation control is included within each assay. It is prepared by mixing 0.1ml of the test organism, 0.1ml reference control to give a final concentration of 0.056% (w/v) formaldehyde and 0.8ml WHO hard water. A neutralisation control is included within each assay. It is prepared immediately following the contact time by mixing 0.1ml disinfectant sample with 0.8ml neutralising diluent; 0.1ml virus control is then added.

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Preparation of Test Substance

MS Megades Novo, Batch/Lot number 190529-01 was tested at 1:99, 1:132, 1:199 and 1:399 as requested. An initial x10 concentration of the disinfectant was prepared on the day of testing in sterile WHO hard water. 0.1ml of the concentrated disinfectant was then added to 0.8ml of sterile WHO hard water. Then 0.1ml of ASFV was added to each disinfectant solution and mixed, therefore resulting in the final concentration of the disinfectant solution. Disinfectant controls were prepared as described above but without the presence of the virus and substituting cell growth media. A virus control and a reference control were prepared for each test as described above.

Test Exposure Conditions

The disinfectant(s) and controls were incubated for 30 minutes at 4 °C.

Test System Recovery

Following the completion of the exposure period, five serial tenfold dilutions of the test substance mixtures and the untreated controls were prepared in PBS. 0.2 ml of each dilution was inoculated into three separate well plates containing confluent test organism. 2 ml Avicel liquid medium was added to each well of the plates.

Incubation and Observation

The cultures and controls were incubated at 37 °C for 6 days. Following incubation, the cells were fixed and stained using crystal violet solution.

Study Retention

The original raw data for this study will be archived at The Pirbright Institute, Ash Road, Pirbright, Surrey GU24 0NF for a minimum of seven years.

The test substance will be retained at The Pirbright Institute, Ash Road, Pirbright, Surrey GU24 0NF for a minimum of six months. European Registration Office B.V will be responsible for long term retention of the sample.

Results

Lot Number	Concentration	Estimated Reduction in Titre (Log ₁₀)
MS Megades Novo, 190529-01	1:99	Undetermined*
MS Megades Novo, 190529-01	1:132	Undetermined*
MS Megades Novo, 190529-01	1:199	Undetermined*
MS Megades Novo, 190529-01	1:399	>2**

* Please note that due to cytotoxicity present at this concentration, the virucidal effect of the product could not be determined.

**Please note we could not verify the exact contact time.

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Conclusion

The product **MS Megades Novo**, effectively inactivated over 2 log₁₀ (99%) of African swine fever virus at the dilution of 1:399 (one part disinfectant to three hundred and ninety nine parts of hard water) at 4°C.

Directive and Disclaimer

This report has been prepared based on information available to The Pirbright Institute at the time of preparation. The log reduction and/or percentage reduction must be specified in all marketing relating to this products effectiveness against ASFV. The Pirbright Institute does not endorse any products.

Test Reported by: ISRAEL STOKES Disinfectant testing laboratory technician

Signed. I Stokes Date 3/10/19

Checked By: LORRAINE FROST Technical manager of disinfectant testing

Signed. [Signature] Date 3rd OCTOBER 2019

LORRAINE FROST
TECHNICAL MANAGER, DISINFECTANT TESTING
Non-vesicular Disease Reference Laboratory
The Pirbright Institute
GU24 0NF



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The Pirbright Institute Ash Road, Pirbright, Woking, GU24 0NF UK
t +44 (0)1483 232411 f +44 (0)1483 232448 e enquiries@pirbright.ac.uk

Preventing and controlling viral diseases
www.pirbright.ac.uk