ATS LABS

FINAL STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Avian Influenza A (H3N2) virus (Avian Reassortant)

PRODUCT IDENTITY

Penetone XF-7117
Lot CL-802-141 and Lot CL-802-142

DATA REQUIREMENTS

U.S. EPA 40 CFR Part 158,
"Data Requirements for Registration"
Pesticide Assessment Guidelines - Subdivision G, 91-2(f)

PROTOCOL NUMBER

SRC16101907.AFLU

AUTHOR

Kelleen Gutzmann, M.S.
Study Director

STUDY COMPLETION DATE

May 14, 2008

PERFORMING LABORATORY

ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

SPONSOR

Penetone Corporation
700 Gotham Parkway
Carlstadt, NJ 07072

SPONSOR REPRESENTATIVE

Scientific & Regulatory Consultants, Inc.
102 1/2 South Chauncey Street
Columbia City, IN 46725-2306

PROJECT NUMBER

A06072

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Project Number: A06072

Protocol Number: SRC16101907.AFLU

Sponsor: Penetone Corporation
700 Gotham Parkway
Carlstadt, NJ 07072

Sponsor Representative: Scientific & Regulatory Consultants, Inc.
102 1/2 South Chauncey Street
Columbia City, IN 46725-2306

Testing Facility: ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance Name: Penetone XF-7117

Lot/Batch(s): Lot CL-802-141 and Lot CL-802-142

Test Substance Characterization
Test substance characterization as to content, stability, solubility, storage, etc., is the responsibility of the Sponsor. (See Attachment I: Sponsor Test Material Characterization.)

STUDY DATES

Date Sample Received: March 3, 2008
Study Initiation Date: March 13, 2008
Experimental Start Date: March 25, 2008
Experimental End Date: April 1, 2008
Study Completion Date: May 14, 2008

OBJECTIVE

The objective of this study was to evaluate the virucidal efficacy of a test substance against Avian Influenza A (H3N2) virus (Avian Reassortant) according to test criteria and methods approved by the United States Environmental Protection Agency (U.S. EPA) for registration of a product as a virucide.

SUMMARY OF RESULTS

Test Substance:	Penetone XF-7117, Lot CL-802-141 and Lot CL-802-142
Dilution:	1 oz/gallon (1 part + 128 parts) in 400 ppm AOAC Synthetic Hard Water
Virus:	Avian Influenza A (H3N2) virus (Avian Reassortant), ATCC VR-2072, Strain A/Washingon/897/80 X A/Mallard/New York/6750/78
Exposure Time:	Ten minutes
Exposure Temperature:	Room temperature (20.1°C)
Organic Soil Load:	5% fetal bovine serum
Efficacy Result:	Two lots of Penetone XF-7117 met the test criteria specified in the study protocol. The results indicate **complete inactivation** of Avian Influenza A (H3N2) virus (Avian Reassortant) under these test conditions as required by the U.S. EPA for claims of virucidal activity.

TEST SYSTEM

1. Virus
The A/Washington/897/80 X A/Mallard/New York/6750/78 strain of Avian Influenza A (H3N2) virus (Avian Reassortant) used for this study was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-2072). Stock virus was prepared by collecting the allantoic fluid from inoculated 10 day old fertilized, embryonated chicken eggs. The fluid was clarified by centrifugation, aliquoted and was stored at ≤-70°C until the day of use. On the day of use an aliquot of stock virus (ATS Labs Lot IA-69) was removed, thawed, and maintained at a refrigerated temperature until used in the assay. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Influenza virus on Rhesus monkey kidney cells.

2. Test Cell Cultures
Cultures of Rhesus monkey kidney (RMK) cells were received from ViroMed Laboratories, Inc., Cell Culture Division (ViroMed Lot # K0313). Cultures were maintained and used at the appropriate density in tissue culture labware at 36-38°C in a humidified atmosphere of 5-7% CO_2.

3. Test Medium
The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 1% heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B.

ATS LABS

FINAL STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Newcastle disease virus

PRODUCT IDENTITY

Penetone XF-7117
Lot CL-802-141 and Lot CL-802-142

DATA REQUIREMENTS

U.S. EPA 40 CFR Part 158,
"Data Requirements for Registration"
Pesticide Assessment Guidelines - Subdivision G, 91-2(f)

PROTOCOL NUMBER

SRC16101907.NEW

AUTHOR

Mary J. Miller, M.T.
Study Director

STUDY COMPLETION DATE

May 15, 2008

PERFORMING LABORATORY

ATS Labs
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Eagan, MN 55121

SPONSOR

Penetone Corporation
700 Gotham Parkway
Carlstadt, NJ 07072

SPONSOR REPRESENTATIVE

Scientific & Regulatory Consultants, Inc.
102 1/2 South Chauncey Street
Columbia City, IN 46725-2306

PROJECT NUMBER

A06068

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Project Number: A06068

Protocol Number: SRC16101907.NEW

Sponsor: Penetone Corporation
700 Gotham Parkway
Carlstadt, NJ 07072

Sponsor Representative: Scientific & Regulatory Consultants, Inc.
102 1/2 South Chauncey Street
Columbia City, IN 46725-2306

Testing Facility: ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance Name: Penetone XF-7117

Lot/Batch(s): Lot CL-802-141 and Lot CL-802-142

Test Substance Characterization
Test substance characterization as to content, stability, solubility, storage, etc., is the responsibility of the Sponsor. (Attachment I and Attachment II: Sponsor Test Material Characterization Report)

STUDY DATES

Date Sample Received: March 3, 2008
Study Initiation Date: March 12, 2008
Experimental Start Date: March 21, 2008
Experimental End Date: March 28, 2008
Study Completion Date: May 15, 2008

OBJECTIVE

The objective of this study was to evaluate the virucidal efficacy of a test substance against Newcastle disease virus according to test criteria and methods approved by the United States Environmental Protection Agency (U.S. EPA) for registration of a product as a virucide.

SUMMARY OF RESULTS

Test Substance:	Penetone XF-7117, Lot CL-802-141 and Lot CL-802-142
Dilution:	1 oz/gallon (1 part + 128 parts) in 400 ppm AOAC Synthetic Hard Water
Virus:	Newcastle disease virus, ATCC VR-108, Strain B1, Hitchner or Blacksburg
Exposure Time:	Ten minutes
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	5% fetal bovine serum
Efficacy Result:	Two lots of Penetone XF-7117 (Lot CL-802-141 and Lot CL-802-142) met the test criteria specified in the study protocol. The results indicate **complete inactivation** of Newcastle disease virus under these test conditions as required by the U.S. EPA for claims of virucidal activity.

TEST SYSTEM

1. Virus
The B1, Hitchner or Blacksburg strain of Newcastle disease virus used for this study was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-108). The stock virus was prepared by collecting the allantoic fluid from inoculated ten day old fertilized, embryonated chicken eggs (a protocol deviation). The allantoic fluid was clarified by centrifugation at approximately 1500 RPM for ten minutes at approximately 4°C. The supernatant was removed, aliquoted, and the high titer stock virus was stored at ≤-70°C until the day of use. On the day of use, an aliquot of stock virus (ATS Labs Lot NDV-38) was removed, thawed and maintained at a refrigerated temperature until used in the assay. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Newcastle disease virus on chicken embryo fibroblast cells.

2. Test Cell Cultures
Cultures of chicken embryo fibroblast (CEF) cells (ATS Labs Lot CEF031908) were received from Charles River SPAFAS (Charles River SPAFAS Lot 0854F). The cultures were seeded by ATS Labs personnel and were maintained and used at the appropriate density in tissue culture labware at 36-38°C in a humidified atmosphere of 5-7% CO_2.

3. Test Medium
The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 2% heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, 2.5 µg/mL amphotericin B, 2.0 mM L-glutamine, and 5% tryptose phosphate broth.

ATS LABS

FINAL STUDY REPORT

STUDY TITLE

Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Virus: Porcine Respiratory & Reproductive Syndrome virus (PRRS)

PRODUCT IDENTITY

Penetone XF-7117
Lot CL-802-141 and Lot CL-802-142

DATA REQUIREMENTS

U.S. EPA 40 CFR Part 158,
"Data Requirements for Registration"
Pesticide Assessment Guidelines - Subdivision G, 91-2(f)

PROTOCOL NUMBER

SRC16101907.PRRS

AUTHOR

Mary J. Miller. M.T.
Study Director

STUDY COMPLETION DATE

May 15, 2008

PERFORMING LABORATORY

ATS Labs
1285 Corporate Center Drive, Suite 110
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SPONSOR

Penetone Corporation
700 Gotham Parkway
Carlstadt, NJ 07072

SPONSOR REPRESENTATIVE

Scientific & Regulatory Consultants, Inc.
102 1/2 South Chauncey Street
Columbia City, IN 46725-2306

PROJECT NUMBER

A06069

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Project Number: A06069

Protocol Number: SRC16101907.PRRS

Sponsor: Penetone Corporation
700 Gotham Parkway
Carlstadt, NJ 07072

Sponsor Representative: Scientific & Regulatory Consultants, Inc.
102 1/2 South Chauncey Street
Columbia City, IN 46725-2306

Testing Facility: ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance Name: Penetone XF-7117

Lot/Batch(s): Lot CL-802-141 and Lot CL-802-142

Test Substance Characterization
Test substance characterization as to content, stability, solubility, storage, etc., is the responsibility of the Sponsor. (Attachment I and Attachment II: Sponsor Test Material Characterization Report)

STUDY DATES

Date Sample Received: March 3, 2008
Study Initiation Date: March 12, 2008
Experimental Start Date: March 27, 2008
Experimental End Date: April 3, 2008
Study Completion Date: May 15, 2008

OBJECTIVE

The objective of this study was to evaluate the virucidal efficacy of a test substance against Porcine Respiratory & Reproductive Syndrome virus according to test criteria and methods approved by the United States Environmental Protection Agency (U.S. EPA) for registration of a product as a virucide.

SUMMARY OF RESULTS

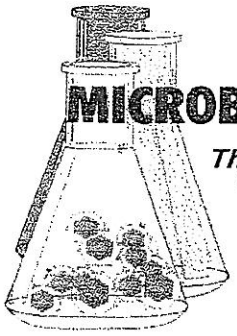
Test Substance:	Penetone XF-7117, Lot CL-802-141 and Lot CL-802-142
Dilution:	1 oz/gallon (1 part + 128 parts) in 400 ppm AOAC Synthetic Hard Water
Virus:	Porcine Respiratory & Reproductive Syndrome virus, Strain NVSL
Exposure Time:	Ten minutes
Exposure Temperature:	Room temperature (20.0°C)
Organic Soil Load:	5% fetal bovine serum
Efficacy Result:	Two lots of Penetone XF-7117 (Lot CL-802-141 and Lot CL-802-142) met the test criteria specified in the study protocol. The results indicate **complete inactivation** of Porcine Respiratory & Reproductive Syndrome virus under these test conditions as required by the U.S. EPA for claims of virucidal activity.

TEST SYSTEM

1. Virus
The NVSL strain of Porcine Respiratory & Reproductive Syndrome virus used for this study was obtained from the University of Kentucky. The stock virus was prepared by collecting the supernatant culture fluid from infected culture cells. The cells were disrupted and cell debris removed by centrifugation at approximately 2000 RPM for five minutes at approximately 4°C. The supernatant was removed, aliquoted, and the high titer stock virus was stored at ≤-70°C until the day of use. On the day of use, an aliquot of stock virus (ATS Labs Lot PRR-23) was removed, thawed and maintained at a refrigerated temperature until used in the assay. The stock virus culture contained 5% fetal bovine serum as the organic soil load. The stock virus tested demonstrated cytopathic effects (CPE) typical of Porcine Respiratory & Reproductive Syndrome virus on MARC-145 cells.

2. Test Cell Cultures
Cultures of MARC-145 cells (ATS Labs Lot MC031808) were originally obtained from National Veterinary Services Laboratories, Ames, Iowa. The cells were propagated by ATS Labs personnel. The cells were seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO_2.

3. Test Medium
The test medium used in this study was Minimum Essential Medium (MEM) supplemented with 5% heat-inactivated fetal bovine serum (FBS), 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B.



MICROBIOTEST, INC

The Microbiology and Virology Laboratory

Volume _____

FINAL REPORT

Virucidal Effectiveness Test
Porcine Circovirus Type 2 (PCV-2)

Test Agent
Penetone XF-7117

Data Requirements
EPA Guidelines 810.2100 (g)

Author
Tien V. Mai

Study Completion Date
02/27/2008

Performing Laboratory
MICROBIOTEST
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TEST CONDITIONS

Challenge virus:
Porcine Circovirus Type 2 (PCV-2), Iowa State University

Host:
PT-1 cells, American BioResearch Laboratories

Organic load:
Viral stock contained ≥5% organic load

Active ingredient in test product:
9.6% quats

Neutralizer used:
Fetal bovine serum + 0.5% Polysorbate 80 + 0.2% Lecithin + 0.5% Glycine

Contact time:
10 minutes

Contact temperature:
24C (Ambient temperature)

Dilution:
1.0 oz/gallon – 1:128 (1 part test agent + 127 parts diluent)

Diluent:
400 ppm ± 2.9% AOAC hard water

Carrier Inoculation:
Test carriers were inoculated with 0.6mL viral stock and dried for 55 minutes at 24C

Media and reagents:
RPMI 1640 containing 5% fetal bovine serum
Phosphate Buffered Saline (PBS)
Fetal bovine serum + 0.5% Polysorbate 80 + 0.2% Lecithin + 0.5% Glycine
Tissue culture alcohol
400 ppm ± 2.9% AOAC hard water
Anti-PCV conjugate
PBS containing 0.5% Fetal bovine serum
Sephacryl S-1000 columns

RESULTS (continued)

Table 6
Log_{10} Reduction

Test product	Penetone XF-7117 Lot No. CL-712-117	Penetone XF-7117 Lot No. CL-712-118
Log_{10} reduction	≥ 3.20	≥ 3.20

CONCLUSIONS

According to the regulatory agencies, the test agent passes the Virucidal Effectiveness Test if there is complete inactivation of the challenge virus at all dilutions. When cytotoxicity is evident, at least a three-log reduction in titer must be demonstrated beyond the cytotoxic level.

When tested as described, Penetone XF-7117 (Lot No. CL-712-117) and Penetone XF-7117 (Lot No. CL-712-118) passed the Virucidal Effectiveness test when Porcine Circovirus Type 2, containing at least 5% organic load, was exposed to the test product for 10 minutes at 24C. All controls met the criteria required for a valid test. These conclusions are based on observed data.

ATS LABS

FINAL STUDY REPORT

STUDY TITLE

AOAC Use-Dilution Method

Test Organisms:

Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)

PRODUCT IDENTITY

Penetone XF-7117 (Mod 1)
Lot C807-203 (>60 days old), Lot 810-280A and Lot 810-280B

DATA REQUIREMENTS

U.S. EPA 40 CFR Part 158
"Data Requirements for Registration"
Pesticide Assessment Guidelines - Subdivision G, 91-2 (c)

PROTOCOL NUMBER

SRC16102308.UD

AUTHOR

Joy Salverda, B.S.
Study Director

STUDY COMPLETION DATE

January 26, 2009

PERFORMING LABORATORY

ATS Labs
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SPONSOR

Penetone Corporation
700 Gotham Parkway
Carlstadt, NJ 07072

PROJECT NUMBER

A07105

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: AOAC Use-Dilution Method

Project Number: A07105

Protocol Number: SRC16102308.UD

Sponsor: Penetone Corporation
700 Gotham Parkway
Carlstadt, NJ 07072

Test Facility: ATS Labs
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

TEST SUBSTANCE IDENTITY

Test Substance Name: Penetone XF-7117 (Mod 1)

Lot/Batch(s): Lot C807-203 (>60 days old), Lot 810-280A and Lot 810-280B

Test Substance Characterization
Test substance characterization as to content, stability, etc., (40 CFR, Part 160, Subpart F [160.105]) is the responsibility of the Sponsor. Sponsor Test Material Characterization Reports may be found in Attachments I, II, and III. Per the Sponsor, Lot CL807-203, Lot CL810-280A and Lot CL810-280B as specified in the Test Material Characterization Reports are the same as Lot C807-203, Lot 810-280A and Lot 810-280B, respectively.

STUDY DATES

Dates Samples Received: July 16, 2008 (Lot C807-203 (>60 days old))
October 30, 2008 (Lot 810-280A and Lot 810-280B)
Study Initiation Date: November 13, 2008
Experimental Start Date: December 15, 2008
Experimental End Date: December 18, 2008
Study Completion Date: January 26, 2009

OBJECTIVE

The objective of this study was to determine the efficacy of the Sponsor's product following the AOAC Use-Dilution Method in compliance with the U.S. Environmental Protection Agency requirements set forth in the Pesticide Assessment Guidelines.

SUMMARY OF RESULTS

Test Substance:	Penetone XF-7117 (Mod 1) (Lot C807-203 (>60 days old), Lot 810-280A and Lot 810-280B)
Dilution:	1 oz / gallon (1+128 parts) in 400 ppm AOAC Synthetic Hard Water
Test Organisms:	*Staphylococcus aureus* (ATCC 6538) *Salmonella enterica* (ATCC 10708)
Exposure Time:	Ten minutes
Exposure Temperature:	20 ± 1°C (20.0°C)
Organic Soil Load:	5% fetal bovine serum
Efficacy Result:	Penetone XF-7117 (Mod 1) demonstrated efficacy of three lots against *Staphylococcus aureus*, and therefore, meets the requirements set forth by the U.S. EPA for disinfectant label claims following a ten minute exposure period. Penetone XF-7117 (Mod 1) demonstrated efficacy of three lots against *Salmonella enterica*, and therefore, meets the requirements set forth by the U.S. EPA for disinfectant label claims following a ten minute exposure period.

STUDY MATERIALS

Test System/Growth Media

Test Organism	ATCC #	Growth Medium
Staphylococcus aureus	6538	Synthetic Broth
Salmonella enterica	10708	Synthetic Broth

The microorganisms used in this study were obtained from the American Type Culture Collection, Manassas, Virginia.

Recovery Media

Neutralizing Subculture Medium: Letheen Broth + 0.07% Lecithin + 0.5% Tween 80
Agar Plate Medium: Tryptic Soy Agar with 5% Sheep Blood (BAP)

Reagents

Organic Soil Load Description: 5% fetal bovine serum (FBS)

Hard Water Description:
The sponsor specified 400 ppm AOAC Synthetic Hard Water was made using 16.8 mL of AOAC Solution 1 and 16.0 mL of AOAC Solution 2. The total volume of the solution was brought to approximately 4 L using filter sterilized deionized water. The Synthetic Hard Water was prepared, titrated, and used for testing on day of preparation. The actual titration result was 396 ppm.