ATS LABS

FINAL STUDY REPORT

STUDY TITLE

Determination of Available Chlorine, pH and Hypochlorous Acid Concentration

PRODUCT IDENTITY

Ultra-Lyte
UL-15, UL-16, UL-17, UL-18 and UL-19

DATA REQUIREMENTS

U.S. Environmental Protection Agency, Office of Prevention, Pesticides, and Toxic Substances (OPPTS), Product Properties Test Guidelines

AUTHOR

Amy S. Jeske, B.S.
Study Director

STUDY COMPLETION DATE

April 29, 2010

PERFORMING LABORATORY

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

SPONSOR

Clarentis LLC
23969 NE SR3, Suite G # 143
Belfair, WA 98528

SPONSOR REPRESENTATIVE

Plains ECA Solutions
RR1 Decker Manitoba
R0M 0K0 Canada

PROJECT NUMBER

A09183

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA Section 10 (d) (1) (A), (B), or (C).

Company: Clarentis LLC

Company Agent: _____

_____
Title

_____ Date: _____
Signature

GOOD LABORATORY PRACTICE STATEMENT

The study referenced in this report was conducted in compliance with U.S. Environmental Protection Agency Good Laboratory Practice (GLP) regulations set forth in 40 CFR Part 160.

The studies not performed by or under the direction of ATS Labs are exempt from this Good Laboratory Practice Statement and include: characterization and stability of the compounds that are not outlined in this protocol.

Submitter:_____ Date:_____

Sponsor:_____ Date:_____

Study Director: Amy S Jeske Date: 4/29/10
Amy S. Jeske, B.S.

QUALITY ASSURANCE UNIT SUMMARY

Study: Determination of Available Chlorine, pH and Hypochlorous Acid Concentration

The objective of the Quality Assurance Unit is to monitor the conduct and reporting of nonclinical laboratory studies. These studies have been performed under Good Laboratory Practice regulations (40 CFR Part 160) and in accordance to standard operating procedures and standard protocols. The Quality Assurance Unit maintains copies of study protocols and standard operating procedures and has inspected this study on the dates listed below. Studies are inspected at time intervals to assure the integrity of the study.

Phase Inspected	Date	Study Director	Management
Critical Phase	March 12, 2010	March 12, 2010	April 28, 2010
Final Report	April 27, 2010	April 27, 2010	

The findings of these inspections have been reported to management and the Study Director.

Quality Assurance Auditor: _____ Date: 4/28/10

TABLE OF CONTENTS

STUDY PERSONNEL

STUDY DIRECTOR:	Amy S. Jeske, B.S.
Professional personnel involved:	
Scott R. Steinagel, B.S.	- Manager, Microbiology Laboratory Operations
Anne Stemper, B.S.	- Research Scientist I
Adam Pitt, B.S.	- Research Assistant II
Peter Toll, B.S.	- Research Assistant II
Erin Hawkinson, B.S.	- Research Assistant I

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Determination of Available Chlorine, pH and Hypochlorous Acid Concentration

Project Number: A09183

Protocol Number: CLS01030210.CUST.1

Sponsor:
Clarentis LLC
23969 NE SR3, Suite G #143
Belfair, WA 98528

Sponsor Representative:
Plains ECA Solutions
RR1 Decker Manitoba
R0M 0K0 Canada

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

TEST SUBSTANCE IDENTITY

Test Substance Name: Ultra-Lyte

Lot/Batch(s): UL-15, UL-16, UL-17, UL-18 and UL-19

Test Substance Characterization
Test substance characterization not outlined in this protocol is the responsibility of the Sponsor.

STUDY DATES

Date of Test Substance Preparation: March 11, 2010
Study Initiation Date: March 9, 2010
Experimental Start Date: March 11, 2010
Experimental End Date: March 12, 2010
Study Completion Date: April 29, 2010

OBJECTIVE

The objective of this study was to determine the (free) available chlorine, pH and to calculate the hypochlorous acid concentration of a Sponsor's product.

TEST HISTORY

The test substances used in this protocol were prepared at ATS Labs on March 11, 2010. The initial samples Ultra-Lyte lots UL-10, UL-11, UL-12, UL-13 and UL-14 were expected to contain approximately 525 ppm of available chlorine when they were supplied to ATS Labs. Upon titration, ATS determined that UL-10 was more concentrated than indicated by the Sponsor. At that time, the Sponsor decided to replace Ultra-Lyte lots UL-10, UL-11, UL-12, UL-13 and UL-14, with new samples also prepared at ATS Labs (see Amendment 1). The results of the pH assessment for Ultra-Lyte lots UL-10, UL-11, UL-12, UL-13 and UL-14 and partial titration of Ultra-Lyte lot UL-10 can be found in Table 4: Supplemental Data for Lots Not Used in Study.

TEST PRINCIPLE

The concentration of available chlorine in the test substance was determined by a colorimetric sodium thiosulfate titration method. Potassium iodide (KI) and sulfuric acid (H_2SO_4) are added to an aliquot of test substance and mixed. The solution was then titrated with sodium thiosulfate and starch indicator was added to enhance the visualization of the endpoint. The pH of each test substance lot was determined in triplicate at 25±1°C using a calibrated pH probe capable of measuring pH to ±0.05. The hypochlorous acid concentration of each test substance lot was calculated using the average pH and available chlorine as determined in testing.

TEST METHOD

Based on the Sponsor's expected concentration range, triplicate samples of each test substance lot were transferred to individual vessels and were titrated. The weight of sample transferred to each vessel was determined by the following calculation:

$$\text{Weight of sample (in grams)} = \frac{(\text{N of titrant}) \times (15\text{ mL titrant}) \times (\sim 36\text{ g Cl*/Eq}) \times 1000}{(\text{Theoretical ppm of NaOCl solution to be titrated})}$$

**NOTE: This equation was used when analyzing for NaOCl or available chlorine. An approximate molecular weight for either available chlorine or NaOCl was included.*

The approximate amount of sample was transferred, as calculated above, to three clean vessels. (An alternate number of replicates were performed per Sponsor's request.) 10.0 mL of 10% KI solution and 10.0 mL of 10% H_2SO_4 was transferred to each vessel and the vessels were mixed. The buret was filled with the titrant, ~0.1N Sodium thiosulfate (0.1003N). The titrant was added to the vessel, mixing with additions. The titrant continued to be added until a pale yellow color emerged. Once the pale yellow color was achieved, a four drops of starch indicator was added and mixed. A dark purple and/or blackish color emerged. The titration continued until a clear endpoint was achieved. The volume of titrant added from the buret was read. This procedure was repeated for all remaining vessels. The actual ppm value was determined by averaging the ppm results from each replicate. Results were rounded to the nearest whole ppm.

pH

The test substances were prepared on site at ATS and tested as Ready-To-Use (RTU). Three replicate pH determinations were made for each lot of test substance. The pH measurements were conducted at room temperature using a temperature compensating probe and a pH meter capable of measuring pH to ± 0.05. At least two NIST traceable reference buffers, 4.00, 7.00 and 10.00, were used to calibrate the pH meter prior to sample analysis.

RESULTS

The results of the chemical tests from the test procedure section of this protocol are reported in Tables 1-3.

CALCULATIONS

To calculate the available chlorine concentration (FAC):

$$\text{ppm available Cl} = \frac{\text{(mL titrant used) x (N of titrant) x (35.45 g Chlorine/Eq) x 1000}}{\text{(actual sample weight in grams)}}$$

Once calculated, the ppm values for replicate titrations may be averaged and reported.

N of titrant = Normality of the Sodium thiosulfate using four significant digits *(i.e. 0.1000N)*

To calculate the percent hypochlorous acid (HOCL):

$$\% \text{ HOCL} = 100 \times [\, 1 + K_l/(H^+)]^{-1}$$

Where: K_l is the dissociation constant of HOCL at 20°C or 2.621×10^{-8} mol/L
(H^+) is the negative $\log_{10}$ of the average pH value per lot

To calculate the percent of available HOCL:

$$\% \text{ Available HOCl} = \frac{\% \text{ FAC x \%HOCl}}{100}$$

STATISTICAL METHODS: Arithmetic averages and standard deviation were used when applicable.

PROTOCOL CHANGES

Protocol Amendments:

1.1 Per Sponsor's request, this protocol is amended to include a Sponsor Representative. The name and address of the Sponsor Representative are as below:

Plains ECA Solutions
RR1 Decker Manitoba
R0M 0K0 Canada

1.2 Per Sponsor's request, this protocol is amended to replace the test substance Ultra-Lyte UL-10, UL-11, UL-12, UL-13 and UL-14 with Ultra-Lyte UL-15, UL-16, UL-17, UL-18 and UL-19

2. This protocol is amended to correct an error in the calculation for determining the percent of Available HOCl. The equation should read as below:

$$\% \text{ Available HOCl} = \frac{\% \text{ FAC x \%HOCl}}{100}$$

Protocol Deviations:
Under the Test Principle section of the protocol, it states that the pH of the test substance will be determined using triplicate samples per lot which have been equilibrated to 25±1°C and a calibrated pH probe capable of measuring pH to ±0.05. The temperature range for this determination was inadvertently left in the protocol. For this study, the pH of each test substance was determined at room temperature, which is a deviation from what is stated in the protocol. This protocol deviation did not have an impact on the outcome of the study and is considered acceptable because the pH of each test substance was determined using a temperature compensating probe and the appropriate NIST traceable buffers were also used.

STUDY RETENTION

Record Retention
All of the original raw data developed exclusively for this study shall be archived at ATS Labs, 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121. These original data include, but are not limited to, the following:

1. Certified copy of final study report.
2. Original signed protocol.
3. Any protocol amendments/deviation notifications.
4. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
5. All measured data used in formulating the final report.
6. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
7. Study specific SOP deviations made during the study.

Test Substance Retention
The test substances will be discarded following study completion per Sponsor approved protocol. It is the responsibility of the Sponsor to retain a sample of the test material.

REFERENCES

1. ATS Labs SOP # CGT-0090, "Sodium Hypochlorite Preparation and Sodium Hypochlorite / Available Chlorine Determination", current version.
2. Code of Federal Regulations, 40 CFR 158.
3. Eaton AD, *et. al.* 2005. Standard Methods For the Examination of Water and Wastewater, 21st edition. Washington DC: American Public Health Association.
4. *Handbook of Chemistry and Physics*, CRC Publishing Co., Boca Raton, FL, 58th Edition.
5. ASTM E70-97, "Standard Test method for pH of Aqueous Solutions with the Glass Electrode", 2002.
6. ATS Labs SOP # PCT-8030, "pH Measurement", current version.

ANALYSIS AND CONCLUSION

Ultra-Lyte, UL-15, was determined to have an average free available chlorine of 0.0546%, an average hypochlorous acid of 94.1%, an average available hypochlorous acid of 0.0514% and an average pH of 6.38.

Ultra-Lyte, UL-16, was determined to have an average free available chlorine of 0.0539%, an average hypochlorous acid of 94.3%, an average available hypochlorous acid of 0.0508% and an average pH of 6.36.

Ultra-Lyte, UL-17, was determined to have an average free available chlorine of 0.0539%, an average hypochlorous acid of 94.5%, an average available hypochlorous acid of 0.0509% and an average pH of 6.35.

Ultra-Lyte, UL-18, was determined to have an average free available chlorine of 0.0526%, an average hypochlorous acid of 93.8%, an average available hypochlorous acid of 0.0493% and an average pH of 6.40.

Ultra-Lyte, UL-19, was determined to have an average free available chlorine of 0.0544%, an average hypochlorous acid of 94.5%, an average available hypochlorous acid of 0.0514% and an average pH of 6.35.

In the opinion of the Study Director, there were no circumstances that may have adversely affected the quality or integrity of the data.

TABLE 1: pH RESULTS

Sample	Run	pH	Average pH
Ultra-Lyte UL-15	1	6.39	6.38
	2	6.37	
	3	6.38	
Ultra-Lyte UL-16	1	6.34	6.36
	2	6.37	
	3	6.37	
Ultra-Lyte UL-17	1	6.34	6.35
	2	6.36	
	3	6.36	
Ultra-Lyte UL-18	1	6.41	6.40
	2	6.39	
	3	6.41	
Ultra-Lyte UL-19	1	6.33	6.35
	2	6.35	
	3	6.36	

TABLE 2: TITRATION RESULTS

Sample		Sample Mass (g)	Volume of Titrant Used to Reach the End Point (mL)	ppm Free Available Chlorine	Average ppm Free Available Chlorine
Ultra-Lyte UL-15	Run # 1	108.25	16.8	552	546
	Run # 2	99.84	15.3	545	
	Run # 3	99.73	15.2	542	
Ultra-Lyte UL-16	Run # 1	99.99	15.2	541	539
	Run # 2	100.09	15.3	544	
	Run # 3	99.07	14.8	531	
Ultra-Lyte UL-17	Run # 1	99.53	15.1	539	539
	Run # 2	99.82	15.2	541	
	Run # 3	99.84	15.1	538	
Ultra-Lyte UL-18	Run # 1	99.73	14.7	524	526
	Run # 2	99.96	14.8	526	
	Run # 3	99.24	14.7	527	
Ultra-Lyte UL-19	Run # 1	100.06	15.3	544	544
	Run # 2	100.26	15.3	543	
	Run # 3	100.02	15.3	544	

ppm = parts per million

TABLE 3: CALCULATED RESULTS

Sample		Average Percent Free Available Chlorine	Average pH	Average Percent Hypochlorous Acid	Average Percent Available Hypochlorous Acid
Ultra-Lyte UL-15	Run # 1	0.0546	6.38	94.1	0.0514
	Run # 2				
	Run # 3				
Ultra-Lyte UL-16	Run # 1	0.0539	6.36	94.3	0.0508
	Run # 2				
	Run # 3				
Ultra-Lyte UL-17	Run # 1	0.0539	6.35	94.5	0.0509
	Run # 2				
	Run # 3				
Ultra-Lyte UL-18	Run # 1	0.0526	6.40	93.8	0.0493
	Run # 2				
	Run # 3				
Ultra-Lyte UL-19	Run # 1	0.0544	6.35	94.5	0.0514
	Run # 2				
	Run # 3				

TABLE 4: SUPPLEMENTAL DATA FOR LOTS NOT USED IN STUDY

Sample	Run	pH	Average pH
Ultra-Lyte UL-10	1	6.16	6.17
	2	6.16	
	3	6.19	
Ultra-Lyte UL-11	1	6.22	6.23
	2	6.22	
	3	6.26	
Ultra-Lyte UL-12	1	6.23	6.24
	2	6.24	
	3	6.24	
Ultra-Lyte UL-13	1	6.24	6.24
	2	6.23	
	3	6.24	
Ultra-Lyte UL-14	1	6.28	6.29
	2	6.28	
	3	6.31	

Sample	Run	Sample Mass (g)	Volume of Titrant Used to Reach the End Point (mL)	ppm Free Available Chlorine
Ultra-Lyte UL-10	1	41.63	7.6	649
	2	40.77	7.4	645

ppm = parts per million

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AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	2
Effective Date:	3/16/10
Sponsor:	Clarentis LLC 23969 NE SR3, Suite G # 143 Belfair, WA 98528
Sponsor Representative:	Plains ECA Solutions RR1 Decker Manitoba R0M 0K0 Canada
Test Facility:	ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	Determination of Available Chlorine, pH and Hypochlorous Acid Concentration
ATS Labs Protocol Number:	CLS01030210.CUST.1
ATS Labs Project Number:	A09183

EXACT COPY
INITIALS M DATE 4-28-10

Modifications to Protocol:

This protocol is amended to correct an error in the calculation for determining the percent of Available HOCl. The equation should read as below:

$$\% \text{ Available HOCl} = \frac{\% \text{ FAC} \times \% \text{HOCl}}{100}$$

Changes to the protocol are acceptable as noted.

Amy S. Jeske
Study Director

3/16/10
Date

ATS LABS

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AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	1
Effective Date:	3/11/10
Sponsor:	Clarentis LLC 23969 NE SR3, Suite G # 143 Belfair, WA 98528
Test Facility:	ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	Determination of Available Chlorine, pH and Hypochlorous Acid Concentration
ATS Labs Protocol Number:	CLS01030210.CUST.1
ATS Labs Project Number:	A09183

EXACT COPY
INITIALS JK DATE 4-28-10

Modifications to Protocol:

1. Per Sponsor's request, this protocol is amended to include a Sponsor Representative. The name and address of the Sponsor Representative are as below:

   Plains ECA Solutions
   RR1 Decker Manitoba
   R0M 0K0 Canada

2. Per Sponsor's request, this protocol is amended to replace the test substance Ultra-Lyte UL-10, UL-11, UL-12, UL-13 and UL-14 with Ultra-Lyte UL-15, UL-16, UL-17, UL-18 and UL-19

Changes to the protocol are acceptable as noted.

Sponsor — Date: 3-11-10

Study Director — Date: 3/11/10

(For Laboratory Use Only)
ATS Labs Project # A 0 9 1 8 3
EM3/9/10

PROTOCOL

Determination of Available Chlorine, pH and Hypochlorous Acid Concentration

PROTOCOL NUMBER

CLS01030210.CUST.1

EXACT COPY
INITIALS MP DATE 4-28-10

PREPARED FOR

Clarentis LLC
23969 NE SR3, Suite G # 143
Belfair, WA 98528

PERFORMING LABORATORY

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

PREPARED BY

Amy S. Jeske, B.S.
Manager, Microbiology Operations

DATE

March 2, 2010

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1285 Corporate Center Drive, Suite 110 • Eagan, MN 55121 • 877.287.8378 • 651.379.5510 • Fax: 651.379.5549

Determination of Available Chlorine, pH and Hypochlorous Acid Concentration

SPONSOR: Clarentis LLC
23969 NE SR3, Suite G # 143
Belfair, WA 98528

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

PURPOSE
The purpose of this study is to determine the (free) available chlorine, pH and to calculate the hypochlorous acid concentration of a Sponsor's product.

TEST SUBSTANCE CHARACTERIZATION
The Sponsor will be responsible for all test substance characterization that is not outlined in this protocol.

SCHEDULING AND DISCLAIMER OF WARRANTY
Experimental start dates are generally scheduled on a first-come/first-serve basis once ATS Labs receives the Sponsor approved/completed protocol, signed fee schedule and corresponding test substance(s). Based on all required materials being received at this time, the proposed experimental start date is March 11, 2010. Verbal results may be given upon completion of the study with a written report to follow on the proposed completion date of April 2, 2010. To expedite scheduling, please be sure all required paperwork and test substance documentation is complete/accurate upon arrival at ATS Labs.

If a test must be repeated, or a portion of it, due to failure by ATS Labs to adhere to specified procedures, it will be repeated free of charge. If a test must be repeated, or a portion of it, due to failure of internal controls, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test substance and/or test system require modifications due to complexity and difficulty of testing.

If the Sponsor requests a repeat test, they will be charged for an additional test.

Neither the name of ATS Labs or any of its employees are to be used in advertising or other promotion without written consent from ATS Labs.

The Sponsor is responsible for any rejection of the final report by the United States FDA or EPA concerning report format, pagination, etc. To prevent rejection, Sponsor should carefully review the ATS Labs final report and notify ATS Labs of any perceived deficiencies in these areas before submission of the report to the regulatory agency. ATS Labs will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

TEST PRINCIPLE

The concentration of available chlorine in the test substance will be determined by a colorimetric sodium thiosulfate titration method. Potassium iodide (KI) and sulfuric acid (H_2SO_4) are added to an aliquot of test substance and mixed. The solution is then titrated with sodium thiosulfate. Starch indicator is added to enhance the visualization of the endpoint. The pH of the test substance will be determined using triplicate samples per lot which have been equilibrated to 25±1°C and a calibrated pH probe capable of measuring pH to ± 0.05. The hypochlorous acid concentration will be calculated using the average pH and available chlorine as determined in testing.

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TEST PROCEDURE

Based on the Sponsor's expected concentration range, triplicate samples (or other specified number) of each test substance will be transferred to individual vessels and will be titrated. The weight of sample to be transferred to each vessel is determined by the following calculation:

$$\text{Weight of sample (in grams)} = \frac{\text{(N of titrant) x (15 mL titrant) x (~36 g Cl*/Eq) x 1000}}{\text{(Theoretical ppm of NaOCl solution to be titrated)}}$$

**NOTE: This equation may be used when analyzing for NaOCl or available chlorine. An approximate molecular weight for either available chlorine or NaOCl was included.*

Transfer the approximate amount of sample (as calculated above) to at least three clean vessels. (An alternate number of replicates may be performed per Sponsor's request.) Transfer 10 mL of 10% KI solution and 10 mL of 10% H_2SO_4 to each vessel and mix the vessels. A dark yellow/brown color will emerge. Fill the buret with ~0.1N Sodium thiosulfate (the titrant). (An alternate normality of Sodium thiosulfate may be used where appropriate.) Begin adding the titrant to the vessel, mixing with additions. Continue adding the titrant until a pale yellow color emerges. Once the pale yellow color is achieved, add a few drops of starch indicator and mix. A dark blackish color will emerge. Continue titrating until a clear end-point is achieved. Read the volume of titrant added from the buret. Repeat this procedure for all remaining vessels. The actual ppm value will be determined by averaging the ppm results from each replicate. Results will rounded to the nearest whole ppm.

pH

The test substance(s) will be tested as Ready-To-Use. At least three replicate pH determinations will be made. The pH measurements will be conducted at room temperature using a temperature compensating probe and a pH meter capable of measuring pH to ± 0.05. At least two NIST traceable reference buffers surrounding the theoretical range will be used to calibrate the pH meter prior to sample analysis.

RESULTS

The results of the chemical tests from the test procedure section of this protocol will be reported in the final report.

CALCULATIONS

To calculate the available chlorine concentration (FAC):

$$\text{ppm available Cl} = \frac{\text{(mL titrant used) x (N of titrant) x (35.45 g Chlorine/Eq) x 1000}}{\text{(actual sample weight in grams)}}$$

Once calculated, the ppm values for replicate titrations may be averaged and reported.

N of titrant = Normality of the Sodium thiosulfate using four significant digits *(i.e. 0.1000N)*

To calculate the percent hypochlorous acid (HOCL):

$$\% \text{ HOCL} = 100 \times [\, 1 + K_i/(H^+)]^{-1}$$

Where: K_i is the dissociation constant of HOCL at 20°C or 2.621×10^{-8} mol/L
(H^+) is the negative $\log_{10}$ if the average pH value per lot

To calculate the percent of available HOCL:

$$\% \text{ Available HOCl} = 100 \times [\% \text{ FAC} \times \% \text{HOCl}]$$

STATISTICAL METHODS: Arithmetic averages and standard deviation will be used when applicable.

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REPORT

The final report will include but will not be limited to: the names of scientific supervisory personnel involved in the study, the dates of the study initiation and completion, the purpose as stated in the approved protocol, deviations from the protocol, a description of the test method, identification, description and storage of the test and control substances, and data interpretation which may include negative, positive or equivocal results.

PROTOCOL CHANGES

If it becomes necessary to make changes in the approved protocol, the revision and reasons for changes will be documented, reported to the Sponsor and will become a part of the permanent file for that study. Similarly, the Sponsor will be notified as soon as possible whenever an event occurs that may have an effect on the validity of the study.

Standard operating procedures used in this study will be the correct effective revision at the time of the work. Any minor changes to SOPs (for this study) or methods used will be documented in the raw data and approved by the Study Director.

PRODUCT DISPOSITION

It is the responsibility of the Sponsor to retain a sample of the test substance. All unused test substance will be discarded following study completion unless otherwise indicated by Sponsor.

RECORD RETENTION

Study Specific Documents

All of the original raw data developed exclusively for this study shall be archived at ATS Labs. These original data include, but are not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of final study report.
7. Study-specific SOP deviations made during the study.

Facility Specific Documents

The following records shall also be archived at ATS Labs. These documents include, but are not limited to, the following:

1. SOPs which pertain to the study conducted.
2. Non study-specific SOP deviations made during the course of this study which may affect the results obtained during this study.
3. Methods which were used or referenced in the study conducted.
4. QA reports for each QA inspection with comments.
5. Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
6. Current curriculum vitae, training records, and job descriptions for all personnel involved in the study.

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REFERENCES

1. ATS Labs SOP # CGT-0090, "Sodium Hypochlorite Preparation and Sodium Hypochlorite / Available Chlorine Determination", current version.
2. Code of Federal Regulations, 40 CFR 158.
3. Eaton AD, *et. al.* 2005. Standard Methods For the Examination of Water and Wastewater, 21st edition. Washington DC: American Public Health Association.
4. *Handbook of Chemistry and Physics*, CRC Publishing Co., Boca Raton, FL, 58th Edition.
5. ASTM E70-97, "Standard Test method for pH of Aqueous Solutions with the Glass Electrode", 2002.
6. ATS Labs SOP # PCT-8030, "pH Measurement", current version.

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03/04/2010 14:50 FAX 5617763106 ☑003

STUDY INFORMATION

(All sections must be completed prior to submitting protocol)

Sponsor (Date/Initial): 3-3-10 JL

Test Substance (Name and Batch Number - exactly as it should appear on final report):
Ultra-Lyte cc ASS 3/9/10 UL-10 ① Ultra-Lyte UL-10, UL-11, UL-12 UL-13 and UL-14

Expiration Date: 3-10-11

Product Description to be Evaluated:
- ☐ Sodium hypochlorite
- ☑ Available chlorine

Theoretical ppm of sample(s) upon submission: 500 ppm

Active Concentration of NaOCl or Available Chlorine (upon submission to ATS Labs): ① ~500 ppm

Type of Sample (circle one): Manufacturing Use Product or (End-Use Product) or Active Ingredient ①

Storage Conditions
- ☑ Room Temperature
- ☐ 2-8°C
- ☐ Other _____

① clarified per email dated 3/5/10 ASS 3/9/10

Hazards
- ☑ None known: Use Standard Precautions
- ☐ Material Safety Data Sheet, Attached for each product
- ☐ As Follows: _____

Number of Titration replicates per sample
- ☑ 3 replicates
- ☐ Other _____

Number of pH replicates per sample
- ☑ 3 replicates
- ☐ Other _____

03/04/2010 14:50 FAX 5617763106 ☑002

TEST SUBSTANCE SHIPMENT STATUS

☐ Has been used in one or more previous studies at ATS Labs .
☐ Has been shipped to ATS Labs (but has not been used in a previous study).
Date shipped to ATS Labs:_____ Sent via *overnight* delivery? θ Yes θ No
☑ Will be shipped to ATS Labs.
Date of expected receipt at ATS Labs: 3-11-10
☐ Sender (if other than Sponsor):_____

COMPLIANCE

If the Sponsor chooses to conduct the study under GLP compliance (EPA 40 CFR, Part 160 - Good Laboratory Practice Standards), the study will be inspected during at least one critical phase and the final report audited by the ATS Labs Quality Assurance unit.

☑ **GLP:** This study will be conducted per **GLP** regulations.

☐ **Non-GLP:** This study will be **non-GLP** but will be conducted to be compliant with this protocol and all applicable ATS Labs standard operating procedures.

PROTOCOL MODIFICATIONS

☑ Approved without modification
☐ Approved with modification - Supplemental Information Form Attached - ☐ Yes ☐ No

APPROVAL SIGNATURES

SPONSOR:

NAME: Duke Van Kalken (Clarentis LLC) TITLE: President

SIGNATURE: Duke van Kalken DATE: 3-3-10

PHONE: 561-827-4142 (cell) FAX: ~~561-799-9219~~ EMAIL: dukevankalken@hotmail.com

For confidentiality purposes, study information will be released only to the sponsor/representative signing the protocol (above) unless other individuals are specifically authorized in writing to receive study information.

Other individuals authorized to receive information regarding this study: θ See Attached

ATS Labs:

NAME: Amy S. Jeske
Study Director

SIGNATURE: Amy S Jeske DATE: 3/9/10
Study Director