

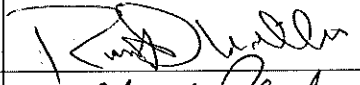
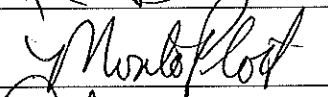
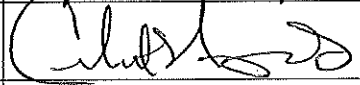

	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Validation Protocol		
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,Approvals

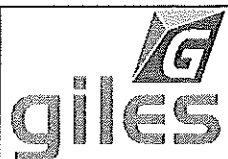
Signing below indicates agreement that the protocol is ready for execution of the Installation, Operational, and Performance Qualification for Carton Machine #2, Evergreen Model CH5 located at 396 Smathers Street at the Repackaging facility.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		5/28/13
Robert Willis	Maintenance		5/28/13
Monte Plott	Production		5/28/13
Matt Haynes	Operations		5/28/13
Deborah Durbin	Quality		5/28/13

A final summary report that consists of results and conclusions based on the data collected after protocol execution will be written and approved. The executed protocol will be attached behind the report.

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I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the Epsom Salt Carton Machine #2 (Evergreen Serial #3093R), functions as intended throughout its anticipated operating ranges. This protocol sets forth the objectives, methodology, documentation, and test activities needed to complete the Installation Qualification (IQ), Operational Qualification (OQ) and Process Qualification (PQ) for the Epsom Salt Carton Machine #2 located at Giles Chemical Repackaging Unit, 396 Smathers Street, Waynesville, NC.

II. BACKGROUND:

This Epsom Salt Carton Machine Model CH5 (serial #3093R) was manufactured by Evergreen Packaging and purchased used from Dairy Packaging Incorporated in Tampa, FL. Dairy Packaging had the machine modified for use with Epsom Salt and it was installed at Giles in April of 2011. The machine is used to make 3 and 4 pound cartons.

The products that are impacted by this study are all Epsom Salt products manufactured by Giles Chemical.

III. OVERVIEW

No other departments or systems will be affected by the installation or use of this equipment.

The following tests will be performed in this qualification:

Controls/Indicators Verification – to document that Epsom Salt Carton Machine #2 oven, start/stop, and infeed controls operate as described by the manufacture.

Lot code and expiration date verification: Verification of proper imprinting of the lot code and expiration date.

Sealed box: Verification that the Epsom Salt Carton Machine securely seals the carton at both ends.

Fill Weights: Verify that the Epsom Salt Carton Machine is capable of producing a finished product that contains a weight of Epsom Salt with a minimum of the label stated weight.

IV. SYSTEM DESCRIPTION:

A. The Evergreen CH5 will open, bottom seal, fill, and top seal gable top polyethylene coated cartons with Epsom Salt. It is a 2 line system, opening filling, and sealing 2 cartons at a time.

B. Description of Operation

01. The carton blanks are pulled from the infeed magazines by vacuum cups. The vacuum cups open the carton and square it. The blanks are slid onto the forming mandrel by a chain. The mandrel supports the cartons while the carton bottoms are heated, formed, and sealed. Gas fired ovens direct heated air to activated the sealing areas of the cartons. Vacuum cups then slide the bottom sealed cartons from the mandrel into conveyor pockets formed by the two conveying chains.
02. The cartons are indexed down the filler carriage at the same rate as they are unloaded from the mandrels. The top breakers on the filler carriage crease the tops on the sealing lip. The cartons are indexed into the fill stations by the conveyor. Each carton is then filled by an auger type filler. The carton tops are heated, folded, sealed and indexed out to the carton conveyor.
03. On the carton conveyor, the carton is check weighed (and rejected if the weight is below label weight) and the Lot/Expiration information is applied by Continuous Inkjet.
04. The cartons are then manually packed into case packaging.

V. SCOPE

The Installation Operational Performance Qualification protocol is intended to certify with documented evidence that the Epsom Salt Carton Machine #2 is installed, operates, and functions as intended throughout its anticipated operating ranges.

VI. ROLES AND RESPONSIBILITIES

1. Engineering

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- ❖ Write and issue the protocol
 - ❖ Investigate protocol deviation reports
 - ❖ Execute the OQ and manage the data collection for the PQ.
 - ❖ Review raw data and originate interim notification to Quality Assurance
 - ❖ Write and route the final report
2. Quality Assurance
- ❖ Review and approve the protocol.
 - ❖ Review and approve raw data and notifications.
 - ❖ Review, approve, and store the final report.
3. Maintenance
- ❖ Provide Equipment Manuals needed to execute operational qualification.
 - ❖ Review and approve the protocol.
 - ❖ Execute the IQ.
 - ❖ Review and approve raw data and notifications.
 - ❖ Review and approve the final report
4. Production
- ❖ Execute the PQ.
 - ❖ Review and approve the final report.

VII. TEST PROGRAM

A. INSTALLATION QUALIFICATION

Objective

The objective of the installation verification is to document that Epsom Salt Carton Machine #1 is installed as indicated by Evergreen Packaging

Equipment/Materials

Epsom Salt Carton Machine model CH5 (SN 3093R)

Ideal Digital Multimeter Model #61-340 (SN 100100221)

Procedure



Perform each listed below for the Epsom Salt Carton Machine

- Location: Verify that the equipment is situated to allow sufficient room around the machine for access doors and panels to be opened.
- Level: Verify instrument is level.
- Utilities
 - Electrical Requirements: Verify that instrument is receiving its specified Voltage.

Acceptance Criteria

Ensure that the installation is in accordance with the manual's specifications.

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B. OPERATION QUALIFICATION

Objective

The objective of Controls/Indicators Verification is to document that the Epsom Salt Carton Machine #2 operates as indicated by Evergreen Packaging. The controls will be operated to test the ability of the Epsom Salt Carton Machine #2 to provide adequate control for starting/stopping, carton feed, and oven ignition.

Equipment/Materials

Epsom Salt Carton Machine model CH5 (SN 3093R)

Procedure

Test each operation of the Epsom Salt Carton Machine #2

Acceptance Criteria

Verification that start/stop, carton feed, and oven ignition controls function as indicated by operation manual

C. PERFORMANCE QUALIFICATION

Objective

The objective of performance testing is to document that the Epsom Salt Carton Machine #2 performs the function required by Giles Chemical. The final product will be tested to verify:

- That the Epsom Salt Carton Machine firmly seals the carton on both ends.
- That the lot code and expiration date numbers are printed properly and accurately.
- That the fill weights are within the accepted range (3.0+ pounds for 3 pound cartons and 4.0+ pounds for 4 pound cartons).

Equipment/Materials

Epsom Salt Carton Machine model CH5 (SN 3093R)

Empty Carton Blank (for tare)

Scale

Procedure

Run the Epsom Salt Filling Machine on 3 pound cartons for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Examine the finished product and check for:

- That the Epsom Salt Filling Machine firmly seals the carton on both ends.
- That the lot code and expiration date numbers are imprinted properly and accurately.
- That the fill weights are within the accepted range.

Repeat for 4 pound cartons.



Acceptance Criteria

The Epsom Salt Filling Machine firmly seals the carton on both ends.

The Epsom Salt Filling Machine correctly imprints the lot code and expiration date.

That the fill weights are within the accepted range of 3.00+ pounds for 3 pound cartons and 4.00+ pounds for 4 pound cartons.

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VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

- Scale
- Ideal Digital Multimeter Model #61-340 (SN 100100221)

IX. REFERENCE:

Instruction Manual, 6877-E Revision A, Evergreen Packaging Equipment

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**EPSOM SALT FILLING MACHINE: INSTALLATION QUALIFICATION****A. Installation Qualification****01. Location**

- a. Verify that Epsom Salt Filling Machine is positioned properly

LOCATION			
Distance Criterion	Is the current area sufficient to open the access without obstructions (Yes/No)	Verified By	Date
Allow sufficient room around the machine for access doors and panels to be opened			
The machine must be located in an area that is adequately ventilated			
Comments:			

02. Level

- a. It is important to make sure that the Epsom Salt Filling Machine is level.

LEVEL			
Is the unit level? (Yes/No)	Acceptable (Yes/No)	Verified By	Date
Comments:			

03. Utilities

- a. Verify that unit is receiving its specified utility requirements.

UTILITIES			
Electrical			
Specified	Actual	Verified By	Date
460 V for Machine			
115V for Controls			
60 Hz			
Water			
The machine requires a water connection for cooling			
A valve should be located at the inlet to the machine to control flow			
Comments:			

Reviewed By: _____

Date: _____

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EPSOM SALT FILLING MACHINE: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls/Indicators Verification – to document that the Epsom Salt Filling Machine operates as described.

Controls/Indicators Verification				
Description	Function	Did Item function properly (Yes/No)	Verified By	Date
Former				
Controls On/Off	With line power to the machine turned on, the controls switch powers up the control panel			
Vacuum	The vacuum switch applies vacuum to the carton picker manifold to start cartons feeding into the machine. With the vacuum switch off, the machine may be cycled for service checks and warm-up without running cartons.			
Jog/Run	In jog position, and filler auto switch on, the filler will index under control of the fill timer. To "jog" the former, the index start switch must be pressed. In run position, the vacuum pump motor and the start button light will be turned on.			
Carton Feed	When line 1 feed switch is engaged, the carton blanks from line 1 will feed into the machine. When line 2 feed switch is engaged, carton blanks from line 2 will feed. These switches operate independently.			
Oven Ignition	When the oven ignition button is pressed, the ovens ignites and begins heating.			
Comments:				

Reviewed By: _____

Date: _____

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**EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION****C. Firmly Sealed:** Verify That the Epsom Salt Filling Machine firmly seals the carton on both ends.

Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Firmly Sealed					Trial	of 4
Sample #	Is the top sealed? (Yes/No)	Is the top scorched? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the bottom scorched? (Yes/No)	Verified By	Date
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
Comments:						

Reviewed By: _____

Date: _____

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**EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)**

A. Lot Code and Expiration Date Imprinting: Verify that the lot code and expiration date numbers are imprinted properly and accurately.

Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Lot Code and Expiration Date Imprinting			Trial	of 4
Sample #	Is the Lot Code and Expiration Date visible? (Yes/No)	Is the Lot Code and Expiration Date correct? (Yes/No)	Verified By	Date
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
Comments:				

Reviewed By: _____

Date: _____

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**EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)****A. Fill Weights:** Verify that the fill weights are within the accepted range of 3.00+, or 4.00+ pounds (circle one)..

Run the Epsom Salt Filling Machine for 5 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.



Fill Weights			Trial	of 4
Sample #	Actual Weight (Yes/No)	Acceptable (Yes/No)	Verified By	Date
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
Comments:				

Reviewed By: _____

Date: _____

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CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date	Verified By	Date
Scale					
Multimeter					

Reviewed By: _____ Date: _____

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ATTACHMENT I - PROTOCOL DEVIATION REPORT LOG

Log each Protocol Deviation Report in the table below. Attach the PDRs to this Attachment.

PDR #	DESCRIPTION	DATE INITIATED	DATE RESOLVED
Comments:			

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ATTACHMENT II. PROTOCOL DEVIATION REPORT (PDR)

_____ General Information _____

System Name: _____ Protocol Number: _____

Deviation Report Number: _____ Protocol Step & Page No.: _____ -

_____ Instructions _____

1. The validation specialist assigns a sequential report number for each deviation with a specific protocol. For example, 001, 002, etc. can be easily referenced in a report.
2. Reference the relevant protocol number, step and page number of the noted deviation above.
3. Complete the below listed sections. If necessary, use additional pages and attach any supporting info.
4. Include the original PDR(s) with the protocol as an attachment. Summarize the impact of the deviation in the Validation Report.

Description of Deviation:

Investigation Evaluation and Results:

Corrective Action and Resolution:

Overall Investigation Review:

Prepared By: _____ Date: _____

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ATTACHMENT III - SIGNATURE IDENTIFICATION LOG SHEET

Identify in the table below any personnel involved in the execution of this protocol.

[illegible]

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