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|  | GILES CHEMICAL ~ PREMIER MAGNESIA | |  |
| | Company Form | | |
| | Title: Lot Production Records | Number: P15-PR-100-095 | |
| | Owner: Ashley Williams | Revision: 2 | |
| | Effective Date: 07/07/2016 | Page: 1 of 3 | |

1.0 Purpose

The purpose of this procedure is to ensure that all information pertinent to the manufacturing of Epsom salt is properly documented, prepared, collected, reviewed, approved and retained.

2.0 Scope

This procedure is for documenting production records and process controls designed to assure that all Epsom Salt produced has the consistent identity, strength, quality and purity we purport.

3.0 Responsibility

The Manufacturing Plant Manager will collect and assemble the daily production records for products produced and ensure traceability. The documents will be reviewed, signed, and approved by the Quality Unit to ensure proper cGMP and GDP procedures are being followed.

4.0 Safety Considerations

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

N/A

6.0 Procedure



Batch records are reviewed by the Quality Unit for completeness and GDP's. Additionally, a critical review is conducted to ensure compliance with all established procedures prior to release of the lot. This review and approval will be completed before each lot is released.

All Lot Production Records are to be assembled in the following order:

1. *Lot Production Record (P13-FM-100-041)* lists the date, lot number, operators, and a checklist for all applicable documents included in each daily Lot Production Record. This form will be attached to the front of each packet of documents which will contain all production records for that day.
2. *Daily Production Report-Days (P12-FM-100-009a)* lists date, operators, customer, SCR number, product, and amount of product produced on that shift. The Daily Production Report also serves as documentation of label control and certain process checks.
3. *Pallet Count Log (P12-FM-100-010)* is used to count each pallet of product produced.

Controlled Document



Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for the accuracy of the document.

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4. *Daily Production Report-Nights (P12-FM-100-009b)* lists date, operators, customer, SCR number, product, and amount of product produced on that shift. The Daily Production Report also serves as documentation of label control and certain process checks.
5. *Pallet Count Log (P12-FM-100-010)* is used to count each pallet of product produced.
6. *SCR (Special Customer Requirement) Sheets* are used to verify that each product is made to the specifications of the customer.
7. SPC Charts are used to monitor the critical parameters of the process as well as indicate trends and anomalies to better help operators run efficiently and consistently. The following forms are used:
 - a. *Digester pH (P12-FM-100-006b)*
 - b. *Digester Specific Gravity (P12-FM-100-006a)*
 - c. *Process Specific Gravity (P12-FM-100-052)*
 - d. *Crystallizer Temperature Log (P12-FM-100-007)*
 - e. *Dryer Salt Temp (P12-FM-100-005)*
8. *Daily Dryer/Cooler Temperature Log (P15-FM-200-056)* is used to record the Dryer/Cooler temperatures every 30 minutes
9. *Process Check Log (P15-FM-100-055)* is used for periodic checks of crystal production, recovery and waste water, and environmental equipment
10. *Material Handler Log (P12-FM-100-008)* is used for periodic checks of the boilers and air compressors and also to monitor the MgO and Acid supplies
11. *Acid Car History Log (P12-PR-200-F007)* is used to record pertinent information from each Acid railcar that is received including the date, time of spot, railcar number, duration of use, destination, empty verification and release signature.
12. *MgO Car History Log (P12-PR-200-F008)* is used to record pertinent information from each MgO railcar that is received including the date, time of spot, railcar number, duration of use, destination, empty verification and release signature.
13. *Manufacturing Process Quality Audit (P14-QA-100-F090)* is an audit performed by Quality three times per day to ensure the product meets all cGMP, Giles Quality, and customer standards including but not limited to weight specifications, bulk density, and appearance.
14. *Daily SCR Quality Audit (P12-QA-100-F077)* is an audit performed by Quality to ensure all Giles Quality standards and Special Customer Requirements are met prior to shipping. This sheet will only be included in the Lot Production Record on weekdays (Mon-Fri).

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15. *CoA (Weekly Lot #)* is a weekly Certificate of Analysis confirming that product meets USP specifications.

16. *Daily Affirmation Results* are the Lab results confirming the daily sample (taken at 7:00am) has passed USP testing. This sheet is to be signed by the Chemist performing the USP testing.

All documents included in the Lot Production Record must be reviewed, signed, and approved by the Quality Unit.

Each Lot Production Record is stored in the cGMP Library for at least 1 year, it will then be moved to long term storage. Lot Production records must be retained for a minimum of 4 years.

7.0 Reference Documents

Lot Production Record (P13-FM-100-041)
Daily Production Report-Days (P12-FM-100-009a)
Daily Production Report-Nights (P12-FM-100-009b)
Pallet Count Log (P12-FM-100-010)
SCR Sheets (Customer Specific)
Digester pH (P12-FM-100-006b)
Digester Specific Gravity (P12-FM-100-006a)
Process Specific Gravity (P12-FM-100-052)
Crystallizer Temperature Log (P12-FM-100-007)
Dryer Salt Temp (P12-FM-100-005)
Daily Dryer/Cooler Temperature Log (P15-FM-200-056)
Process Check Log (P15-FM-100-055)
Material Handler Log (P12-FM-100-008)
Acid Car History Log (P12-PR-200-F007)
MgO Car History Log (P12-PR-200-F008)
Manufacturing Process Quality Audit (P14-QA-100-F090)
Daily SCR Quality Audit (P12-QA-100-F077)
CoA (Weekly Lot #)
Daily Affirmation Results (Received from the Lab)

8.0 Change Information

Added Quality functions to procedure.

Added the following documents to be included in each Lot Production Record – SCR Sheets, Manufacturing Process Quality Audit, Daily SCR Quality Audit, Weekly CoA, and Daily Affirmation results.

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