
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: Lot Production Records	Number: P15-PR-100-095	
	Owner: Jason Bumgarner	Revision: 0	
	Effective Date: 07/20/15	Page: 1 of 2	

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

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.
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. 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:

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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- 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)*

7. *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
8. *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.
9. *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.
10. *Weekly Clean Day Log (P12-FM-100-017)* is used as a checklist of all items to be cleaned on a weekly basis. This form will only be included in the Lot Production Record once per week.

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)
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)
Material Handler Log (P12-FM-100-008)
Acid Car History Log (P12-PR-200-F007)
MgO Car History Log (P12-PR-200-F008)
Weekly Clean Day Log (P12-FM-100-017)

8.0 Change Information

New Document

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