GILES CHEMICAL ~ PREMIER MAGNESIA



Company Procedure

Number: Q13-PR-100-021

Title: Manufacturing Rework/Reprocessing Procedure

Owner: Ashley Williams Revision: 2

Effective Date: 04/29/2017 Page: 1 of 3



1.0 Purpose

The purpose of this procedure is to describe how to manage product that does not conform to standards or specifications and has been approved for rework or reprocessing. Following this procedure will ensure that the reworked or reprocessed product will be of equivalent quality to that which it was originally produced to meet. Properly reworked or reprocessed product may be shipped in a saleable condition and reduces loss.

2.0 Scope

This procedure applies to any in-process or finished product during Manufacturing. Sources of product approved for rework or reprocessing may include, but not limited to, product determined to be non-conforming, product that has been returned, or damaged/incorrect packaging.

3.0 Responsibility

<u>Quality Unit</u> - is responsible for quarantining, evaluating and approving all product prior to it being reworked or reprocessed and releasing the product upon a final evaluation.

<u>Plant Management/Lead Operator</u> – is responsible for assuring that all personnel involved are properly trained and for ensuring the appropriate steps of this procedure are followed to properly rework or reprocess the identified product.

4.0 Safety Considerations

Always wear facility required PPE including, but not limited to, safety glasses and steel toed boots.

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

1. Any product that is non-conforming, has been returned or has damaged/incorrect packaging will be tagged with *Quality Hold* placards (*Q12-FM-100-002*) and quarantined appropriately by Quality and/or Production.

Controlled Document

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- See Nonconforming Material (Q12-PR-100-017), Returned Products (Q13-PR-100-011), and Quarantine and Auditing of Products (Q12-PR-100-012)
- 2. Quality will evaluate the product and assist Production with investigating the issue. If required, a CAPA will be initiated according to *Corrective and Preventive Action System (Q13-PR-100-014)*. A determination will be made as to which of the following actions will be carried out:

Rework: 1) Product that meets all specifications but has a non-conforming packaging issue that can be corrected without impacting the product. 2) Product that can be redirected to a customer willing to accept the product as is.

- The magnesium sulfate heptahydrate in products that is approved for rework must meet all specifications.
- Rework issues must be related to the product's packaging/labeling and/or Special Customer Requirements (SCR) only (i.e. pallet configurations, print, SCR codes).
- Reworked product must undergo evaluation prior to approval for release.
- The disposition of all reworked product is to be documented so as to maintain traceability.
- Sales must approve the shipment to an alternative customer.

<u>Reprocessing</u>: Product that meets all specifications but cannot be reworked and must be melted down and reintroduced into the beginning of the process as a Raw Material.

- The magnesium sulfate heptahydrate in products that is approved for reprocessing must meet all specifications.
- Reprocessing issues must be related to physical characteristics such as, but not limited to, hard salt, damaged packaging, and crystal size.
- The magnesium sulfate heptahydrate will be reintroduced into the process as a Raw material.
- As a Raw Material the product will be subject to the established manufacturing process including but not limited to filtration and crystallization purification.
- Reprocessed product must undergo evaluation prior to approval for release to ensure that the magnesium sulfate heptahydrate is not OOS.
- The disposition of all reprocessed product is to be documented using the *Daily Production Report Days (P12-FM-100-009a) or Daily Production Report Nights (P12-FM-100-009b)* so as to maintain traceability.



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<u>Scrap (Waste):</u> Any product that does not meet specifications and cannot be reworked or reprocessed.

- Material that is not approved for reprocessing is disposed of.
- While still abiding by local environmental regulations, this product will be sent to the land fill as waste.

Records Retention

Salt Pour Back for Reprocessing Log and supporting documentation will be retained with Production batch records for a period of four years.

7.0 Reference Documents

Quality Hold Placard (Q12-FM-100-002)
Quarantine and Auditing of Products (Q12-PR-100-012)
Nonconforming Material (Q12-PR-100-017)
Corrective and Preventive Action System (Q13-PR-100-014)
Returned Product (Q13-PR-100-011)
Daily Production Report Days (P12-FM-100-009a)
Daily Production Report Nights (P12-FM-100-009b)

8.0 Change Information

Changed document used to record Reprocessed material