
	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Form</b>		
	<b>Title: Label (Barcode &amp; Pre-printed Film)</b> <b>Control for Manufacturing Facility</b>	<b>Number: P13-QA-100-081</b>	
	<b>Owner: Ashley Williams</b> <b>Effective Date: 02/06/2017</b>	<b>Revision: 5</b> <b>Page: 1 of 5</b>	

## 1.0 Purpose

The purpose of this procedure is to ensure the receipt, examination, storage, issuance, return and reconciliation of labels are controlled according to 21 CFR 211.125 & ICH Q7 9.3.

## 2.0 Scope

The definition of labels at the Manufacturing facility pertains to barcode labels and pre-printed film labels.

## 3.0 Responsibility

Warehouse Operator – will notify Material Control Coordinator, who will in turn notify QA, of incoming pre-printed film labels, place incoming labels on Quality Hold and transport labels to and from storage.

QA – inspect pre-printed film labels for identity and conformity, release for use, and approval of label discrepancy investigations.

Lead Operators/Salt Operators - record pre-printed film label values for label reconciliation and generate barcode labels.

Plant Manager – oversee the reconciliation of the quantities of labels issued, used and returned.

Material Control Coordinator - responsible for issuing Shop Packet Worksheets, inventory, cycle count, and initiation of label discrepancy investigations

## 4.0 Safety Considerations

Safety shoes and safety glasses are required when working in the plant.



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

Incoming Raw Material Placards  
 Product /Stock Transfer Sheets  
 Shop Packet Worksheet – Birthing Station  
 Daily Production Report & Batch Record  
 Inventory Control file

### 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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## 6.0 Procedure

### Reception

#### Pre-printed film labels for Form Fill and Seal bagger:

- Warehouse Operator will unload incoming truck and place labels into the designated Quality Hold area or placard with *Incoming Raw Material Hold (Q15-FM-100-012)* placards if the Quality Hold area is full. This designation of Quality Hold is a visual instruction informing that these labels have not completed the incoming raw material inspection and are NOT available to be used in production.
- Warehouse Operator will take BOL from driver and Packing Slip(s) from pallet(s) and verify incoming quantities. Once quantities are verified, Warehouse Operator will sign and date both the BOL and Packing Slip(s). The BOL is returned to the truck driver and the Packing Slip(s) is submitted to the Material Control Coordinator, Plant Manager, or designated drop box. Material Control Coordinator or Plant Manager will compare quantity received against quantity ordered. Product quantity, date of receipt, and purchase order number are recorded in the Inventory file.

#### Barcode Labels:

- N/A

### Examination

#### Pre-printed film labels for Form Fill and Seal bagger:

- Material Control Coordinator will notify Quality of incoming labels to be inspected and released for use in production.
- The Quality Unit will use *Film Check procedure (P12-QA-100-074)* to examine and inspect labels for identity and conformity against a specified master label provided by customer. Once approved, *Incoming Raw Material* placards will be replaced with *Quality Approved (Q13-FM-100-006)* placards.
- Film labels will be assigned a lot number per shipment. Lot number will be recorded on the *Film Use Log (P15-QA-100-F074l)*, which is inserted within the core of each film roll.
- Incoming labels that do not meet specifications will be rejected and *Quality Rejected (Q13-FM-100-007)* placards will be placed on affected pallets. Quantity rejected is not received into inventory and is returned to supplier.
- Obsolete and outdated labels will be destroyed at local recycling facility.

#### Barcode Labels:

- N/A

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### Storage

#### Pre-printed film labels for Form Fill and Seal bagger:

- Labels will be stored following FIFO (First In First Out) until needed to produce an order. Access to the label storage area is limited to authorized personnel.
- As labels are needed to complete an order, Warehouse Operator will retrieve the identified label in the appropriate quantity from storage.
- Warehouse Operator will note on the Product/Stock Transfer sheet the label name and quantity to be transferred to production. Warehouse Operator shall also note which area the labels will be transferred from and which area they will be transferred to.
- Warehouse Operator will transfer requested labels and give the Product/Stock Transfer sheet to the Plant Manager, Material Control Coordinator, or designated drop box so that the label location and quantity can be updated in the inventory system.
- Warehouse Operators check the stock of labels on the production floor and replenish once per week or as needed.

#### Barcode Labels:

- N/A

### Issuance

#### Pre-printed film labels for Form Fill and Seal bagger:

- Lead Operators use the Shop Packet Worksheet to determine which label to use and quantity. Due to film labels being on a roll, an exact quantity of labels is not issued, a roll is issued and the quantity needed for the production run or batch will be consumed from that roll.
- Lead Operator or Salt Operator retrieves the identified roll of film labels to be mounted in the Form Fill and Seal Bagger.
- The appropriate information needed to determine quantity of labels used and waste will be recorded on the *Film Use Log (P12-QA-100-074l)* and in the table on the *Daily Production Report (P12-FM-100-009a & P12-FM-100-009b)* below, which is part of the Batch Record.

Customer	Product Type	CO #	SCR	Amount Produced	Screened Type
Lot# of each Film roll Used		Start Count	End Count	Film Used	Waste

- Label waste generated during production will be disposed of.

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#### Barcode Labels:

- The Material Control Coordinator controls issuance of barcode labels by distributing a Shop Packet Worksheet to the Lead Operators for each order. The Salt Operators generate the barcode label from the information in the Shop Packet Worksheet.
- Barcode label information including, but not limited to, product identification, description, date, time, lot number, temperature and customer order is recorded in the inventory system when the label is birthed.
- Issuance of barcode labels is further controlled in that they should be birthed one at a time as each pallet of packaged product is produced. The barcode label that is birthed with the finished pallet is used for shipping and traceability.
- Once the pallet is shipped the inventory system will then add all customer information to the Inventory Control file.
- If a pallet is rejected or damaged the associated barcode must be destroyed and deleted out of the inventory system.

#### Return

##### Pre-printed film labels for Form Fill and Seal bagger:

- Film Use Log will stay with roll of unused film labels until roll is spent.
- Roll of unused film labels will be returned to designated area and maintained and stored in a manner to prevent mix-ups and provide proper identification.

#### Barcode Labels:

- Any excess barcode labels will be returned to the Material Control Coordinator to be destroyed and deleted out of the Inventory Control file.



#### Reconciliation

##### Pre-printed film labels for Form Fill and Seal bagger:

- Waste label amounts produced on the Form Fill and Seal Bagger are calculated based upon the difference between the quantity of labels used and final product produced.
- Label yield will be calculated from the Daily Production Report. If the yield is less than 90% an investigation should be completed by Plant Manager, Material Control Coordinator, and Quality Unit using the *Label Discrepancy Form (Q15-FM-100-013)*. Investigation should result in the proper explanation of a yield less than 90%.
- Cycle counts will be conducted monthly by Material Control Coordinator with the assistance of Planning and Scheduling Manager.

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#### Barcode Labels:

- Material Control Coordinator will reconcile quantities of labels issued, used, and returned to evaluate discrepancies found between the number of pallets of packaged product and the number of labels issued. Such discrepancies should be investigated and the investigation should be approved by the Quality Unit.
- Cycle counts will be conducted monthly by Material Control Coordinator with the assistance of Planning and Scheduling Manager.

### **7.0 Reference Documents**

*Incoming Raw Material Hold placard (Q15-FM-100-012)*  
*Film Use Log (P12-QA-100-074l)*  
*Daily Production Report (P12-FM-100-009a & P12-FM-100-009b)*  
*Quality Approved placard (Q13-FM-100-006)*  
*Quality Rejected placard (Q13-FM-100-007)*  
*Label Discrepancy Form (Q15-FM-100-013)*

### **8.0 Change Information**

Added Label Discrepancy Form

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