
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: USP Salt Expiry Date	Number: R13-PR-100-030	
	Owner: Brook Vaughn	Revision: 2	
	Effective Date: 08/01/14	Page: 1 of 2	

1.0 Purpose

The purpose of this procedure is to ensure that the expiry period is properly displayed. The Repackaging facility is allowed to consume salt that is 364 days old or less. The regulation will ensure that all salt packaged is within the 4 year expiry period that is supported by stability testing. All salt packaged will also carry a lot number that will allow traceability.

2.0 Scope

This procedure will apply to all in-coming USP salt from Manufacturing to Repackaging.

3.0 Responsibility

Salt Hangers, Line Personnel, Lead Operators, Shift Supervisors, and Quality all have responsibilities executing this procedure. Quality will have the overall responsibility of ensuring compliance.

4.0 Definitions

Expiry Code – Is a date that is stamped on a pouch or carton; the date will reference the month prior to three years since manufacture. EX: Would be if the product was manufactured Feb. 8, 2013, the expiry date would be **EXP 0116 with 01** referring to January and 16 referring to 2016.

Lot Code – the lot code is stamped on each pouch and carton to allow traceability to the production batch to which it was produced. Our products are all stamped with the lot code which is represented by 5 digits. *The first two digits represent the year of production (YY) and the last three digits are the Julian day (JJJ) of the year. July 31st 2014 would be represented by 14212.*

5.0 Safety Considerations

Steel toe shoes, safety glasses, hair net and standard safety attire for the area.

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

6.0 Materials/Equipment



- Date coder at each machine in production

7.0 Procedure

1. Salt Hangers are to verify and document that all salt brought to Repackaging from Manufacturing must be tagged and have a manufacturing date of less than 1 year old from the

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date it will be used at Repackaging. If the date is 1 year or older, it cannot be used in production at Repackaging and will be quarantined until its disposition is determined.

2. Salt Hangers will record in-coming salt information from Manufacturing onto the *Incoming Salt Inspection Form (R12-FM-100-006)*.
3. Repackaging will date code all of its USP production with a 3 year expiration date from the day the product is repackaged. Therefore, when the product expires the salt will actually be within the 4 year expiration of the original manufacture date of the salt.
4. Line personnel will record the date code that is placed on the product on two separate forms, the *Date Code Sign-Off Sheet (R12-FM-100-009)* and the *Daily Audit Sheet (R12-PR-100-F001)*. Quality, Lead Operator and/or Shift Supervisor are responsible to ensure information is recorded properly.
5. All recording documents are kept with Repackaging daily batch records. The date codes are recorded each day on the *Daily Batch Record Sheet (R12-PR-100-F012)*. The batch records are retained for four years.

8.0 Reference Documents

<i>Incoming Salt Inspection Form</i>	<i>(R12-FM-100-006)</i>
<i>Date Code Sign-Off Form</i>	<i>(R12-FM-100-009)</i>
<i>Daily Audit Sheet</i>	<i>(R12 PR-100-F001)</i>
<i>Daily Batch Record Sheet</i>	<i>(R12-PR-100-F012)</i>

9.0 Change Information

Changed Lot Code section to reflect new five digit format and changed the owner of the document.

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