Personnel responsible:
Lead Operator or Technician

Safety:
Safety shoes and safety glasses are required. Other PPE may be required in the specific work area.

Summary:

The standard tests for stability include:

Room Temperature
Oven- 42+/-3 degrees Celsius (3 months @ 45 equivalent to 2 years shelf life)
High Output Florescent Light (14 days is equivalent to 1 year)
UV- 3 days test

Procedures:

Room Temperature

1. Use sealed pouches (or other final packaging as appropriate)
2. Record date, time, and sample product ID number in log book and on stability worksheet.
3. Place sample and control sample on shelf.
4. Evaluate samples for appearance and caking at intervals listed on the stability worksheet (24hr, 48hr, 96hr, 1 Week, 2 Weeks, 1 Month, 2 Months, and 3 Months)
5. The legend on the stability worksheet shows how to rank the evaluation. Compare the sample with the control.
6. At the end 3 Months, the sample will be opened and the odor compared to the oven sample.
7. Record all the data on the stability worksheet.

Oven Aging

8. Press “Stop” on the oven control panel before opening the door.
9. Place the sealed sample and control in the oven.
10. Ensure the control and the sample are clearly marked.
11. Place the control and sample in the oven.
12. Close the door and press “Run” on the oven.
13. Evaluate samples for appearance and caking at intervals listed on the stability worksheet (24hr, 48hr, 96hr, 1 Week, 2 Weeks, 1 Month, 2 Months, and 3 Months)
14. The legend on the stability worksheet shows how to rank the evaluation. Compare the sample with the control.
15. At the end 3 Months, the sample will be opened and the odor compared to the room temperature sample.
16. Record all the data on the stability worksheet.

UV Aging

17. Place sample and control sample on shelf.
18. Turn on UV lamp and place it on the pouches such that the light contacts both the control and the sample in the window if there is a window.
19. Evaluate samples for appearance and caking at intervals listed on the stability worksheet (24hr, 48hr, and 96hr)

20. The legend on the stability worksheet shows how to rank the evaluation. Compare the sample with the control.
21. This test is for 3 days and mainly looking at appearance.

Fluorescent Aging

22. Place sample and control sample on shelf.
23. Turn on the fluorescent lamp and place it on the pouches such that the light contacts both the control and the sample in the window if there is a window.
24. Evaluate samples for appearance and caking at intervals listed on the stability worksheet (24hr, 48hr, 96hr, 1 weeks, and 2 weeks)
25. The legend on the stability worksheet shows how to rank the evaluation. Compare the sample with the control.
26. This test is for 2 weeks and mainly looking at appearance.

Finish

27. At the end of all the aging (3 months), ensure that the stability worksheet is completely filled out.
28. Comment on any findings or anything unusual on the stability worksheet.
29. Retain and file all paperwork for the sample (stability worksheet, blended product batch sheet, and any other pertinent paperwork).
30. Retain samples until they are released for disposal.

TRAINING DOCUMENTATION

	EMPLOYEE	TITLE	SIGNATURE	DATE
1				
2				
3				
4				
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Revision Number	Revision Date	Revision Author	Revision Description
00	10/8/2009	Patrick Owen	Original Document