

GILES CHEMICAL						
PROCEDURE						
	Stability Testing	Page :	1 of 4	Revision Date	:	00 10/8/2009
Author:	Patrick Owen	Work In	structio	n		

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

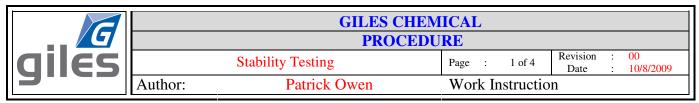
- 1. Use sealed pouches (or other final packaging as appropriate)
- 2. Record date, time, and sample product ID number in log book and on stability worksheet.
- 3. Place sample and control sample on shelf.
- 4. Evaluate samples for appearance and caking at intervals listed on the stability worksheet (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.



GILES CHEMICAL						
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	Stability Testing	Page : 1 of 4	Revision : 00 Date : 10/8/2009			
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TRAINING DOCUMENTATION

	EMPLOYEE	TITLE	SIGNATURE	DATE
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Page : 1 of 4

Revision : Date :

00 10/8/2009

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Work Instruction

Revision Number	Revision Date	Revision Author	Revision Description
00	10/8/2009	Patrick Owen	Original Document