

Test Substance Labeling Concerns

I keep myself up at night worrying about it

Test Substance Labels at a minimum should contain:

- Name
- Batch number
- Expiration date
- Storage conditions



This is a GLP Requirement. It's not just QA being weird.

- If any of the the label requirements are missing, transfer them from the Certificate of Analysis.
- If the COA is missing any of these requirements contact the Study Director
 - Remember the SD doesn't exactly know what you will receive
 - If you have any doubts, call the Study Director, they need to be aware of any concerns

- QA checks the label when we conduct an In-Life Inspection, because we are cool like that
 - We are extremely skeptical of these manufacturer labels
 - If the TS name doesn't exactly match the Protocol we dig a little deeper
 - Give QA some time to check the label during the CPI and confirm that it's the right TS
 - In some cases, the chemical might not be even GLP
- Manufacturers label their TS containers differently, so don't assume the labels to be complete

- Besides a complete label, when you receive the test substance you should also;
 - Check that the TS matches the Protocol for a particular study
 - Check whether or not it will expire before the necessary applications
 - Better to check this upon receipt rather than day of application
 - If your technician picks up the sample make sure they also do these things

- QA will only visit about 30-40% of your trials in any given year

- So, it's your responsibility to make sure the TS label is complete

- It's not a bad time to see if the adjuvant label is complete as well

- Name
 - Concentration
 - Expiration date
 - Storage conditions



- So here's the deal;
 - EPA did find a test substance label without a expiration date at an inspection this year.
 - Even though the study had not yet been submitted, it was written up
 - This is something that they look for, after all it's a GLP requirement
 - Try to make sure that ALL your test substances have the proper labeling in preparation for any EPA inspection you might have



EPA

INSPECTION OBSERVATIONS

ADDRESS/PHONE (EPA OFFICE) Bay 25227

Denver Federal Center
Denver, CO 80225

DATE

PRINTED NAME OF INDIVIDUAL TO WHOM REPORT ISSUED

TO:

Martin J Beran

INVESTIGATION ID NUMBER

2019480119

FIRM NAME AND ADDRESS:

FACILITY INSPECTED ADDRESS

DURING AN INSPECTION / AUDIT OF YOUR FACILITY, THE FOLLOWING POTENTIAL VIOLATIONS WERE OBSERVED BY AGENCY INSPECTORS:

Acct. # of test substances by MSD: 50619203 / 50814001

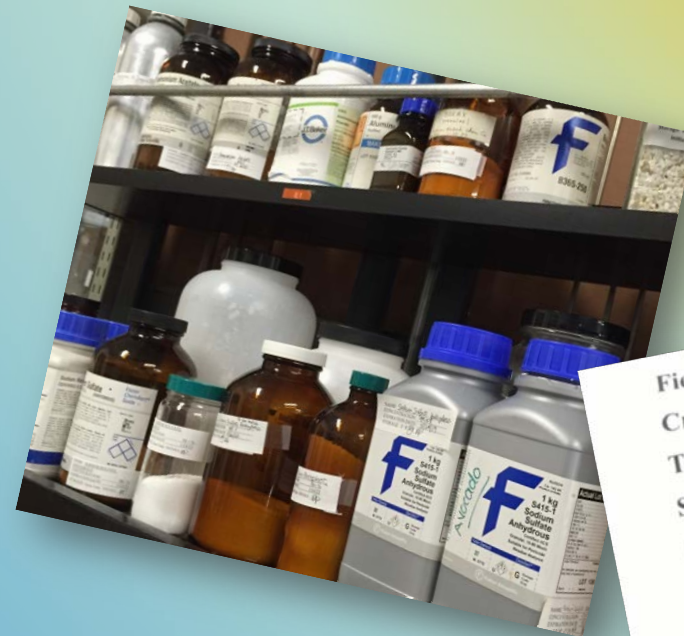
- Test Substance Exp. Date not on Label (on-going study P.R. 12668) 40 CFR 160.105(c)
- Date was added to the container during inspection.

Things You Don't Have to Date and Initial

No, I'm totally serious

You do not need to add initials and date to entries made on:

- Plot Markers
- Sample Bags
- Container Labels
- SOP additions



Field ID # 12545.19 - CA84
Crop Fraction Fruit without pits
Test Substance Difeno. + Cypro.
Sample ID A-difen TRT# 01
Harvest Date 9/30/19
Sample Date 9/30/19
Field Research Director:
Blaine Turner
Name
530 601 0879
Telephone

- These items are not part of the Study Record and are not retained
- You still are free to initial and date these entries, it might be helpful to initial and date to inform about the who and when.
- As a QA, I don't want to dissuade you from this habit.



Rounding

Too Much of a Good Thing

- You can certainly record a rounded calculated value in the Databook. But, don't use that rounded number as you are progressing through a calculation
 - Test Substance amounts
 - Plot Area
 - Output volume
- Using a rounded value can introduce quite a bit of error in the system
- The smaller the rounded value the greater the percentage difference.

NUMBER OF NOZZLES OR HOPPER OUTLETS USED			
MESH SIZE USED IN THE STRAINERS		SPACING BETWEEN NOZZLES OR HOPPER OUTLETS	
NOZZLE BRAND/TYPE/SIZE (e.g. T-JET 8004, even flat fan):			

TREATED AREA² 55 ft x 3.3 ft x 4 passes = 726 ft²

0.017 Acre

²Calculated width of nozzle discharge pattern (CWNDP) at proper boom height X length of plot sprayed or treated. For a broadcast application, CWNDP = (# of nozzles X nozzle spacing). For a banded application, CWNDP = # of nozzles X swath per nozzle. If application is foliar or soil directed enter row width X # of rows X length of plot sprayed or treated; treated row width may differ from actual row width when the actual row width is wider or narrower than local commercial practices. In this circumstance, the application rate should be calculated using a local commercial row width, and an explanation should be included on this page or inserted behind this page. Contact the Study Director if guidance is needed.

$$\boxed{0.017A} \times 333.5 \text{ ml/A} = 5.67 \text{ ml plot}$$

$$35 \text{ gpa} \times 0.017A = 2252 \text{ ml}$$

$$\frac{2252 \text{ ml}}{3000 \text{ ml}} = \frac{5.67 \text{ ml}}{7.55 \text{ ml}}$$

$$125.3 \text{ sec} \times 18.0 \text{ ml/sec} = 2255 \text{ ml}$$

$$\frac{7.50 \text{ ml}}{3007.5 \text{ ml}} = 0.0025 \times 2255 \text{ ml} = \frac{5.62 \text{ ml}}{5.67 \text{ ml plot}} = 99.1\%$$

NUMBER OF NOZZLES OR HOPPER OUTLETS USED			
MESH SIZE USED IN THE STRAINERS		SPACING BETWEEN NOZZLES OR HOPPER OUTLETS	
NOZZLE BRAND/TYPE/SIZE (e.g. T-JET 8004, even flat fan):			

TREATED AREA² 55 ft x 3.3 ft x 4 passes = 726 ft²

0.02 Acre

²Calculated width of nozzle discharge pattern (CWNDP) at proper boom height X length of plot sprayed or treated. For a broadcast application, CWNDP = (# of nozzles X nozzle spacing). For a banded application, CWNDP = # of nozzles X swath per nozzle. If application is foliar or soil directed enter row width X # of rows X length of plot sprayed or treated; treated row width may differ from actual row width when the actual row width is wider or narrower than local commercial practices. In this circumstance, the application rate should be calculated using a local commercial row width, and an explanation should be included on this page or inserted behind this page. Contact the Study Director if guidance is needed.

$$0.02A \times 333.5 \text{ ml/A} = 6.67 \text{ ml plot}$$

$$35 \text{ gpa} \times 0.02A = 2650 \text{ ml}$$

$$\frac{2650 \text{ ml}}{3000 \text{ ml}} = \frac{6.67 \text{ ml}}{7.55 \text{ ml}}$$

$$125.3 \text{ sec} \times 18.0 \text{ ml/sec} = 2255 \text{ ml}$$

$$\frac{7.50 \text{ ml}}{3007.5 \text{ ml}} = 0.0025 \times 2255 \text{ ml} = \frac{5.62 \text{ ml}}{6.67 \text{ ml plot}} = 84.3\%$$

- Fall back to your SOP on Rounding
- Be mindful of documenting rounded values in prompts that they do not end up being used in the calculation
- There will always be a difference in how you calculate and how QA calculates a value. We are trying to maintain a margin of error of 1%
- In a nutshell: Don't round until the final value

Any Questions?

