

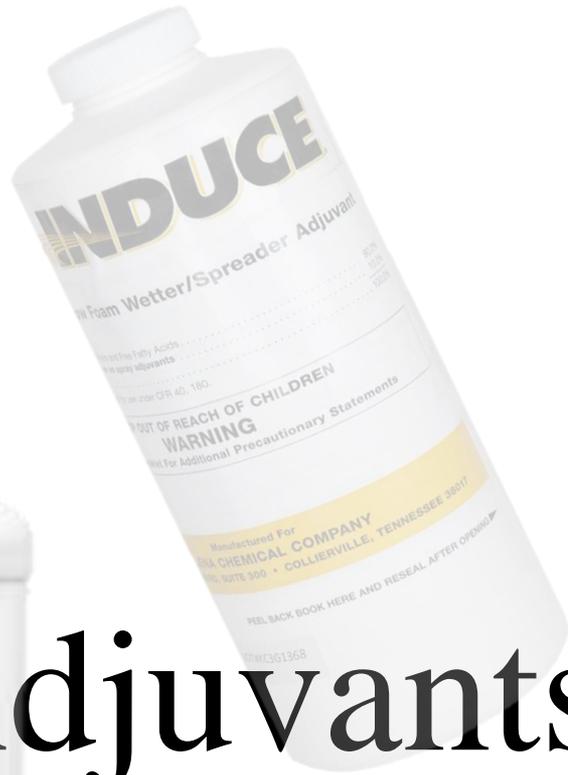
Refining Field GLPs

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Western Region Quality Assurance

- Adjuvant Labeling
- Top Ten Findings
- A Few GLP Reminders
 - Initialing and Dating
 - Updating Facility Documents





Adjuvants



Adjuvants

Why do adjuvants need to be labeled like our test substances?

EPA considers them reagents

Adjuvants

A Reagent is a substance that causes a chemical reaction when added to another substance.



Adjuvants

- **Non-Ionic Surfactants (NIS)** allow water molecules to spread in soil for greater water penetration by breaking surface tension
- **Crop Oil Concentrates (COC)** move the herbicide across the leaf cuticle and reduces surface tension of droplets
- **Methylated Seed Oils (MSO)** more effective at dissolving leaf wax for greater penetration than crop oil concentrates

Adjuvants

They have different labeling requirements than test substances.

All reagents must be labeled to indicate identity, concentration, storage requirements, and expiration date. (40 CFR Part 160.83)

Adjuvants



NAME: Envi-Carb SPE
CONCENTRATION: 0.5g/6 mL
EXPIRATION DATE: 05/12/21
STORAGE: Room Temp. **RP**

Adjuvants

- Most original containers have at least name and concentration printed on the label.
- Storage requirements can be found on accompanying paperwork.
- Expiration date should be assigned by the FRD or contact the manufacturer for expiration confirmation.

Adjuvants

Carrying the Adjuvant containers out to the field:

- Container must have the four requirements
 - Add the rest by using a sticker or wired tag
- Even a smaller secondary bottle must be labeled according to GLPs
- Label must be intact, product information should be legible

WILL MEEKS

90



MODIFIED VEGETABLE OIL SURFACTANT BLEND

PRINCIPAL FUNCTIONING AGENTS:

Methyl esters of C16-C18 fatty acids, polyalkyleneoxide
modified polydimethylsiloxane, alkylphenol ethoxylate 99.0%

CONSTITUENTS INEFFECTIVE AS SPRAY ADJUVANT 1.0%

TOTAL 100.0%

All ingredients are accepted for use under CFR 40, 180.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See Inside Panel for Additional Precautionary Statements

SN 0309/0411

CAS #37281-78-0, 9003-11-6
CA Reg. No. 5905-50071-AA



WILL MEERS 90

UNION-BLENDED VEGETABLE OIL SURFACTANT BLEND

PRECAUTIONARY STATEMENTS:
Irritant to eyes, skin, and mucous membranes.
Avoid contact with eyes, nose, and mouth.
Wash thoroughly with soap and water after use.
Use only as directed. Do not spray to infant.

1990
10/90
10/90

KEEP OUT OF REACH OF CHILDREN
CAUTION

For more information see additional Precautionary Statements



Adjuvants

- In addition, A copy of the adjuvant label must be added to Part 4 in the Field Databook.
- QA will ask to see a copy of this very label

To confirm the rate



Ad-Wet 90

disposed of on site or at an approved waste disposal facility. Triple rinse (or equivalent) during mixing and loading. Recycling decontaminated containers is the best option of container disposal. The Agricultural Container Recycling Council (ACRC) operates the national recycling program. To contact your state and local ACRC recycler, visit the ACRC web page at www.acrcycle.org. Decontaminated containers may also be disposed of in a sanitary landfill.

DIRECTIONS FOR USE

AD-WET 90 is intended for use with pesticides that are labeled for agricultural and non-agricultural uses.

AD-WET 90 cannot be used for aquatic applications. Some pesticide labels recommend a higher or lower surfactant use rate for optimum efficacy. Follow the pesticide label directions when this occurs.

DOSAGE PER 100 GALLONS OF SPRAY MIX:

Herbicides	1 to 3 pints
Defoliants and Desiccants.....	1 to 2 pints
Wettable Powders	1 to 2 pints
Insecticides	3 to 8 ounces
Fungicides.....	3 to 8 ounces
Acaricides.....	3 to 8 ounces

For use with Monsanto glyphosate herbicides refer to the herbicide label for recommended surfactant rates. Do not add this product at a rate which exceeds 5% of the finished spray volume. For wettable powders, water soluble materials and emulsifiable products add AD-WET 90 in water after a good mixture is formed.

Adjuvants

Assigning an Expiration Date:

- IR-4 Advisory #2015-01: Assign a maximum of five years from purchased date.
- Two years is preferable.
- If a lot number is available call the manufacturer to determine expiration date
- If it changes in appearance, replace it.

Adjuvants

In U.S. trials, GLP-compliant equipment must comply with 40 CFR 166, Subpart D, which includes 160.81 (b) (11). Adjuvants in U.S. trials must comply with 40 CFR 160.83.

	X		ADJUVANT LABELING AND RECEIPT INFORMATION (check missing items): Receipt of the adjuvant at the field facility (usually the purchase date): _____ Identity and concentration of the adjuvant (on the adjuvant label): _____ Recommended storage conditions (on the adjuvant label): <input checked="" type="checkbox"/> _____ Expiration date (if not on the label, then assigned by field personnel): _____
X			ENVIRONMENTAL MONITORING DEVICES for test substance storage (FDB Part 4)
		X	GLOBAL POSITIONING DEVICE used to determine plot location (FDB Part 5)

ENVIRONMENTAL MONITORING DEVICES, GLOBAL POSITIONING DEVICES, CALIBRATION EQUIPMENT used to

Adjuvants

Your SOP on Adjuvants should describe;

- What is required on the label
- How to treat secondary containers
- How the expiration date is assigned
- Aliquoting concerns listed in the Advisory

Top Ten 2016 Field Findings



WARNING

The findings, opinions, and fiery diatribe expressed in the following PowerPoint presentation are mostly those of one extremely particular QA and do not necessarily reflect the concerns of other non-Western Region QA or their affiliates.

Number 10

Entries lack initial and date

Number 9

Test Substance label missing
either Storage Conditions or
Expiration Date

Number 8

Plot Markers missing or
not labeled correctly

Number 7

Adjuvant label missing from the
Databook

Number 6

Trial personnel not added to
Part 2A

Number 5

Plot map lacks required
elements or entirely missing

Number 4

Protocol Deviations

Number 3

Stacking trials without
documented approval from the
Study Director

Number 2

Adjuvant label missing certain
specifics

Numero Uno

Test Substance Use Log not
updated at time of application

A Few GLP Reminders

... substances.
... to prevent contamination
... shall be separate areas for:
... and storage of the test, control,

... substances.
... of the test, control, and reference
... es with a carrier, e.g., feed.
... ge of the test, control, and
... ce substance mixtures.

... storage areas for test, control, and/or
... reference substance and for test, control,
... d/or reference mixtures shall be separate
... om areas housing the test systems and shall
... be adequate to preserve the identity,
... strength, purity, and stability of the
... substances and mixtures.

Section 160.49 Laboratory operation areas.
... arate laboratory space and other space shall
... as needed, for the performance of
... ialized procedures required

... or a
... facility environment
... appropriate design
... function according to the pro
... suitably located for operation, inspec
... cleaning, and maintenance.

**Section 160.63 Maintenance and calibration
equipment.**

(a) Equipment shall be adequately
cleaned, and maintained. Equipment
the generation, measurement, or
and/or data shall be adequately test

(b) The written standard operating
procedures required under
160.81(b)(1) shall set fo
detail the methods, mate
to be used in the routine
cleaning, maintenance
and/ or standardization
shall specify, when a
action to be taken
tion of ec

Initialing and Dating

All data entries should be dated on the day of entry and signed or initialed by the person entering the data. (40 CFR Part 160.130)



Initialing and Dating

A Typical Finding:

“Your initials and date are missing from this page. Please add them to the bottom as a late entry.”

Initialing and Dating

MJB 2/28/17 LE

MJB

11/22/16

ABOVE DATA ENTERED BY: _____ DATE: _____

Initialing and Dating

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

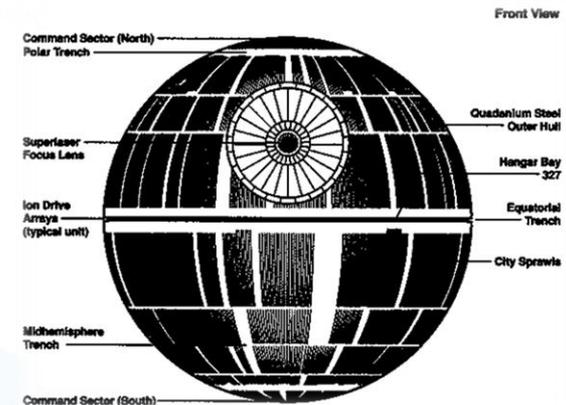
- Plot Markers
- Sample Bags
- Adjuvant Bottles
- Test Substance Labels



Those items are not part of the study record.

Updating Facility Documents

- Organizational Charts particularly at the FRD level should be updated when ever personnel have change.
- Facility Maps should be reviewed for any changes or additions.



Updating Facility Documents

Each testing facility should maintain a current summary of training and experience and job description for each individual engaged in the conduct of a study. (40 CFR Part 160.29)

Updating Facility Documents

- CVs and Job Descriptions should have an initial and date to indicated that they have been reviewed yearly.
- Although Job Descriptions often do not adequately describe your position, being readily available is a GLP requirement.

Updating Facility Documents

- Your Chili Fresh QA needs to make sure study participants have been trained, particularly, in the regulations.
- So, if your Training Records included a GLP training event please add that to the title.
- If QA does not see a GLP event in your training records, we will ask the question.

Questions?

