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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 13 1987

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7G3479/7H5523. Myclobutanil on apples and grapes.
Amendment of 7/28/87. [RCB#'s 2606, 2607, 2608]

FROM: Richard Loranger, Chemist *R. Loranger*
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Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Lois Rossi/Larry Schnaubelt, PM Team 21
Registration Division (TS-767)
and
Toxicology Branch
Hazard Evaluation Division (TS-769)

This review has been expedited at the request of Edwin Tinsworth, Director, Registration Division (8/6/87 memo to Anne Barton).

In reply to our 6/16/87 review Rohm and Haas Company has provided revised Sections B and F for their petition for temporary tolerances for residues of the fungicide myclobutanil on apples, grapes, and animal products. Our final conclusions and recommendation are listed below. Following the latter the actual deficiencies from our previous review will be restated followed by the petitioner's response and our comments/conclusions.

CONCLUSIONS

These conclusions are numbered to correspond to the deficiencies in our 6/16/87 review.

- 1a. The Rally 60DF and 40W labels now specify the same application rates.
- 1b. Details concerning spray volumes will not be required for approval of the current EUP as applications of myclobutanil to apples and grapes have already been completed.
- 1c. The "fresh market only" restrictions have been dropped from the labels as requested.

4b/4c/4d. Appropriate tolerances have now been proposed for residues of myclobutanil and its metabolites in raisin waste, apple pomace and grape pomace.

5. Acceptable tolerances have also been proposed for residues of myclobutanil in meat, milk, poultry and eggs.

RECOMMENDATION

Toxicological considerations permitting we can now recommend for the establishment of the following temporary tolerances:

For residues of alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile and its metabolites containing both the chlorophenyl and triazole rings in or on the following:

Apple pomace-5 ppm	Grape pomace-5 ppm
Raisins-5 ppm	Raisin waste-15 ppm

For residues of alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile in or on the following:

Meat, fat and meat by-products (except liver) of cattle, goats, hogs, horses and sheep	0.04 ppm
Liver of cattle, goats, hogs, horses and sheep	0.2 ppm
Milk	0.02 ppm
Meat, fat, and meat by-products of poultry	0.02 ppm
Eggs	0.02 ppm

Our previous review noted that the established temporary tolerances of 0.5 ppm for apples and grapes are still adequate.

The registrant should also be informed that for extension of this EUP or establishment of permanent tolerances the apple label must have more details on determining spray volumes. Rohm and Haas is advised to consult the attachment to this review when preparing future labels for tree crops. We prefer the concept of tree row volume to that of tree height as suggested on the 60DF draft label.

DETAILED CONSIDERATIONS

Deficiency 1a

The 60DF product has lower individual application rates than the wettable powder, but higher doses per season for both apples and grapes. Therefore, considerably more applications per season would be permitted for the DF product. The petitioner should reexamine the labels to determine if all the rates are truly as intended. The 60DF label should also include an "oz ai per acre" rate for individual treatments of apples.

Petitioner's response: A corrected label is submitted for the 60DF product showing the proper rates.

Our comments/conclusion: The rates for the two products are now essentially identical with individual treatments being 0.8-1 oz ai/100 gallons for apples and 0.8-2 oz ai/acre for grapes. The seasonal maxima for apples and grapes are 32 and 9.6 oz ai/acre, respectively. We note that an "oz ai per acre" rate is still absent from the 60DF label for individual sprays of apples. Although we will not require its presence for this experimental use, it must be on any labels for permanent registration.

Deficiency 1a has been resolved.

Deficiency 1b

More details should be given on the labels in regard to spray volumes for apples. Directions are needed for both dilute sprays (i.e., to runoff) and concentrate sprays.

Petitioner's response: A draft commercial label for the 60DF product is enclosed containing more details regarding spray volume. We do not believe this revision should be required for the EUP label as spraying under this program has been completed.

Our comments/conclusion: We concur that details on spray volume are not necessary for the EUP at this point since applications have been completed. However, for any extension of this EUP or the establishment of permanent tolerances, instructions on determining spray volumes will be required. We note that the draft commercial label includes instructions based mainly on tree height. We consider use of tree row volume (TRV) a more accurate procedure. The petitioner is advised to consult the attachment to this review for preparation of future labels for tree crops.

Deficiency 1b has been resolved.

Deficiency 1c

The "fresh market only" restrictions on the labels are contradictory to the request for byproduct tolerances and should be deleted. Revised labels should be more legible than those in the present submission.

Petitioner's response: Revised labels for Rally™ 60DF, Rally 40W and Rally 40W Water Soluble Pouches are enclosed.

Our comments/conclusion: The new labels are more legible and the fresh market only restriction has been deleted. We had not previously seen the Soluble Pouch label. This product is to be used on grapes at the same rate as the other two materials. Since this formulation also has a longer pre-harvest interval (21 days), we have no objections to its use on grapes.

Deficiency 1c has been resolved.

Deficiencies 4b, 4c, 4d

Although the proposed tolerances of 1 ppm and 5 ppm for wet and dry grape pomace, respectively, are reasonable, it is current practice to set only one pomace tolerance covering both byproducts. A revised Section F should be submitted listing a tolerance for "grape pomace" at 5 ppm. The 1 ppm wet grape pomace tolerance should be deleted.

The 5 ppm food additive tolerance for raisins is adequate. However, the raisin waste tolerance should be changed to 15 ppm to avoid fractional tolerances greater than 1 ppm.

As with grapes, the 1 ppm feed additive tolerance for wet apple pomace should be deleted. Also, the 5 ppm dry apple pomace tolerance should be changed to "apple pomace".

Petitioner's response: A revised Section F with the suggested tolerances is submitted.

Our comments/conclusion: The appropriate tolerances have now been proposed. Deficiencies 4b, 4c and 4d have been resolved.

Deficiency 5

Most of the proposed tolerances for residues of RH-3866 plus its metabolites in animal commodities are higher than necessary. The following tolerances should be proposed in a revised Section F under a separate heading specifying residues of myclobutanil only:

Meat, fat and meat byproducts (except liver) of cattle, goats, hogs, horses and sheep	0.04 ppm
Liver of cattle, goats, hogs, horses and sheep	0.2 ppm
Milk	0.02 ppm
Meat, fat and meat byproducts of poultry	0.01 ppm
Eggs	0.01 ppm

Petitioner's response: A revised Section F is enclosed with the requested tolerances with the exception of poultry tissues and eggs. We prefer 0.02 ppm (2x detection limit for parent) for these commodities to avoid a minor interferent being misinterpreted as a violative residue.

Our comments/conclusion: The above tolerances for animal products are acceptable for this EUP. Deficiency 5 is resolved. We note that the additional studies to be reviewed in PP#7F3476 and the method trial in our labs will determine what permanent animal tolerances are appropriate.

Attachment-Copy to PM 21 only

cc: Circu, RF, PP#7G3479, K. Arne, Reviewer, PMSD/ISB
RDI:Section Head:ARRathman:8/11/87:RDSchmitt:8/11/87
TS-769:RCB:557-7324:RAL:ral(12):CM#2:RM.810>Date:8/11/87

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Guidance for Orchard Spray Application

As a guidance to any future orchard spray applications, the petitioner should incorporate one or more of the following concepts in their submissions as the means of instructing the users on how to vary the quantity of a.i./acre that is needed for different tree sizes.

Procedure 1. For High Volume (HV) Spray Applications to Orchards

Determine volume/A to spray orchard to run-off. Use so much active ingredient/ 100 gal and multiply this number by the volume/A to spray your orchard to runoff to determine the amount of active ingredient/A.

For Example:

Step 1: Use rate (determined by petitioner).....0.5 lb act/100 gal.

Step 2: To spray one acre of your orchard to run-off...300 gal/A.

Step 3: The amount of lb a.i./acre in 300 gal of water is 1.5 lb (0.5 lb act/100 gal x 300 gal/A).

Procedure 2. Estimation of Tree Row Volume (TRV) to Calculate the Gallons/A Needed to Spray to Run-off

Step 1: $43,560/\text{between-row spacing (ft)} = \text{feet of row/acre.}$

Step 2: $\text{Feet of row/acre} \times \text{tree height (ft)} \times \text{cross-row limb spread (ft)} = \text{cu ft of TRV/acre.}$

Step 3: Select one of the following numbers that best indicate the canopy density of each separate orchard or block:

0.70 gal/1,000 cu ft: Trees extremely open, light visible through entire tree, less than 15 scaffold limbs/tree or young tree.

0.75 gal/1,000 cu ft: Trees very open, 18 - 21 scaffold limbs/tree, light penetration throughout tree, healthy spurs within tree canopy.

- 0.80 gal/1,000 cu ft: Trees well pruned, adequate light in trees for healthy spurs throughout trunk and scaffold limbs, many holes in foliage where light can be seen through tree.
- 0.85 gal/1,000 cu ft: Trees moderately well pruned, reasonable spur population within canopy, tree thick enough that light cannot be seen through bottom two-thirds of tree.
- 0.90 gal/1,000 cu ft: Trees pruned minimally, spurs inside canopy are weak due to limited light, very few holes where light can be seen through the tree.
- 0.95 gal/1,000 cu ft: Little or no pruning, spurs dead or very weak in canopy, very little light visible through tree.
- 1.00 gal/1,000 cu ft: Tree totally unpruned, extremely thick, no light visible anywhere through tree canopy, trees more than 20 ft high.

$$\text{Step 4: } \frac{\text{cu ft of TRV/acre (from Step 2)} \times \text{density (from Step 3)}}{1,000}$$

= gal of dilute solution to be applied/A.

Step 5: Using the volume of spray to run-off calculated in Step 4 above, calculate the lb a.i./acre using the formula of Procedure 1 (Step 3).

For Example: An orchard has rows spaced 25 ft apart, tree height is 20 ft, and cross row limb spread is 17 ft. The tree density is 0.85.

Step 1: $43,560 \text{ ft}^2 / 25 \text{ ft} = 1,742.4 \text{ ft}$

Step 2: $1,724.4 \text{ ft} \times 20 \text{ ft} \times 17 \text{ ft} = 592.416 \text{ cu ft}$

Step 3: Density has been given as 0.85

scaffold limbs/tree or young tree.

Step 4: $(592.416 \times 0.85) / 1,000 = 503.5 \text{ gal/acre}$

Step 5: Using the volume of spray to run-off calculated in Step 4 above, calculate the lb a.i./acre using the formula of Procedure 1 (Step 3).

Procedure 3. Estimation of Gallons of Pesticide Spray Solution per acre to Spray to Run-off or LV Application at the Full Leaf Stage of Canopy Using the following Table

Approximate number of gallons of pesticide spray liquid needed per acre for coverage at the full leaf stage of canopy development in tree fruit orchards using high volume (HV) dilute sprays and low volume (LV) concentrate sprays applied with airblast sprayers

Tree height (ft) X	Spray Type	Gallons Per Acre ^a												
		distance between tree rows (ft)												
Tree width (ft) ^b		16	18	20	22	24	26	28	30	32	34	36	38	40
80	HV	152	136											
	LV	20 ^c	17 ^c											
100	HV	191	169	152										
	LV	25	22 ^c	20 ^c										
150	HV	256	254	229	208	191								
	LV	37	33	29	27	25								
200	HV	... ^d	...	305	277	254	235	218						
	LV	39	36	33	30	28						
250	HV	346	317	293	272	254	238				
	LV	45	41	38	35	33	31				
300	HV	416	381	352	327	305	286	269	254	241	229
	LV	53	49	45	42	39	37	35	33	31	29
350	HV	445	411	381	356	334	314	296	281	267
	LV	57	53	49	46	43	40	38	36	34
400	HV	469	436	407	381	359	339	321	305
	LV	60	56	52	49	46	44	41	39
450	HV	490	457	429	404	381	361	343
	LV	63	59	55	52	49	46	44
500	HV	508	476	448	424	401	381
	LV	65	61	58	54	52	49
550	HV	524	493	466	441	419
	LV	67	63	60	57	54
600	HV	538	508	481	457
	LV	69	65	62	59

^a See text for full details of calculation. All values rounded to the nearest whole gallon. Based on standard dosage volumes of 0.7 gallon per 1,000 cu ft TRV for HV and 0.09 gallon for LV sprays. Trees which have a very dense foliar canopy may require slightly more spray volume than shown.

^b Where small trees are interplanted with large trees in the same row, use only the large tree dimensions.

^c LV applications of less than 25 gallons per acre are not generally recommended because of other factors affecting coverage.

^d Data not given because the combination of this tree size on this planting density is unlikely.

Reference: Unrath, C. R., and T. B. Sutton. North Carolina State University, Raleigh, NC 27695. Bulletin AG 37.

The amount of a.i./acre can be calculated by using the volume of spray to run-off per acre found in the table above into the formula used in Procedure 1 (Step 3) above.

Procedure 4. For Low Volume (LV) and Ultra-low Volume (ULV) Applications to Orchards

Take the amount of a.i./A for orchard calculated from Procedure 1; the TRV estimated from Procedure 2; or the full leaf stage of canopy table from Procedure 3; and add to X gal of water/A for LV applications or Y gal of water and/or other solvent/A. X and/or Y is (are) determined by the petitioner to coincide with the proposed use. Less active ingredient/A is normally required for LV and ULV applications. The lower amount of active ingredient/A, if proposed, should be stated as a fraction of the high volume rate. Residue data must be submitted for all uses proposed on the label. Therefore, LV and/or ULV applications will not be allowed if residue data have been submitted for HV applications only.

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