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OFFICE OF PREVENTION,
PESTICIDES AND TOXIC
SUBSTANCES

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MEMORANDUM

SUBJECT: Water holding time for rice use of Carfentrazone-ethyl, and protocol for fish early life stage study, PC Code: 128712

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CONCLUSIONS

Using a half-life of 10 days for the degradation of total residues of carfentrazone-ethyl in rice paddy water (from the California study), and assuming initial concentrations equal to the day 0 residues measured in the California study, results in an estimated holding time of 58 days for rice paddy water in California (where max. use rate = 0.3 lb ai/Acre; reg # 279-3194) to reach the EC50 (5.9 ppb) for vascular aquatic plants. This value may replace the current label holding time of 69 days for California. Using a half-life of 10 days for the degradation of total residues of carfentrazone-ethyl in rice paddy water (from the California study), along with the day 0 residues measured in the Louisiana study, adjusted to reflect the maximum use rate (0.138 lb ai/Acre; reg # 279-3194) in the Delta region, results in an estimated holding time of 35 days for rice paddy water in the Delta to reach 5.9 ppb. This value may replace the current label holding time of 56

28

days for the Delta region.

For the Fish Early Life Stage study, EFED continues to prefer that the study be conducted under an 18 hour light/6 hour dark exposure regime. EFED also prefers that the study use applied parent F8426, and not applied F8426-chloropropionic acid.

BACKGROUND

FMC Corporation has submitted requests to amend their labels for carfentrazone-ethyl such that the required rice paddy water holding time would be changed from the current minimum of 69 days and 56 days in California and the Mississippi Delta region, to 30 days and 7 days in these regions respectively. The registrant also requested two changes to the protocol for a Fish Early Life Stage study requested by EFED: use of a 12 hour light/12 hour dark cycle instead of the 18 hour light/6 hour dark cycle suggested by EFED; and use of the chloropropionic acid degradate as the test material instead of the parent compound.

DETAILED CONSIDERATIONS

Paddy water holding time:

In order to mitigate the aquatic risks for the most sensitive aquatic organisms (plants) resulting from the rice use, EFED calculated in its Section 3 assessment of carfentrazone-ethyl (F8426)(Carleton, 12/22/99), that a minimum holding time of at least 69 days would be needed after application of carfentrazone-ethyl, before paddy waters can be released into the environment. This calculation was based upon the observed dissipation rate of total toxic residues of carfentrazone-ethyl (F8426 plus F8426-chloropropionic acid, F8426-cinnamic acid, F8426-propionic acid, F8426-benzoic acid, and F8426-3-hydroxymethyl benzoic acid degradates) in rice paddy water (MRID 44654701), compared with the 50% lethality endpoint (EC50) for the most sensitive aquatic species, duckweed (*Lemna gibba*) which was 5.9 ppb (MRID 43849603). Toxicity tests cited in the Section 3 risk assessment revealed somewhat lower toxicities to duckweed than the parent for the degradates of carfentrazone ethyl, with generally decreasing toxicity accompanying increased degradation of the compound. The most toxic of the degradates was the primary, or first sequential degradate, F8426-chloropropionic acid, which had a reported EC50 of 26.2 ppb.

The registrant argues that by calculating the holding time in the manner in which we did, EFED assumed that all metabolites were as toxic as the most toxic material (the parent), which "significantly overestimates the risk". The registrant proposes instead that the holding time be based on comparisons of the concentrations of individual compounds in paddy water against their individual toxicity endpoints. For example, in the previously mentioned California rice paddy water study study, the concentrations of parent and the chloropropionic acid degradate were each

below the EC50s for these compounds (5.9 ppb and 26.2 ppb respectively) by 30 days after application. On this basis, they suggest 30 days as an adequate holding time for paddy water in California. What the registrant fails to consider is that the 5.9 ppb EC50 established for F8426 in duckweed is based upon concentrations of F8426 measured on day 0 of a 14-day static exposure test, at the end of which no measurable concentrations of F8426 remained. In other words, while the test was underway, F8426 was degrading, presumably first to F8426-chloropropionic acid, and followed by further breakdown to other degradates. The 50% lethality therefore actually occurred in response to a *mixture* of parent F8426 and various degradates (probably mostly F8426-chloropropionic acid), the total concentration of which *declined over the course of the study*, and not to F8426 at 5.9 ppb. If time-averaged concentrations of total residues had been determined, the EC50 to duckweed for total residues in this study would actually have been *less than* 5.9 ppb. Thus 5.9 ppb is not a conservative estimate of the EC50 for total residues. The same is true for studies on marine diatoms (*Skeletonema costatum*, MRID 43849604), and freshwater diatoms (*Navicula pelliculosa*, MRID 43849605) in which the EC50s (16 ppb and 6.5 ppb, respectively) were based on nominal concentrations of F8426 measured on day 0, and undetectable on day 14.

An examination of the data from the California and Louisiana rice paddy aquatic dissipation studies shows that the majority of the residues at each sampling time consisted of F8426 and F8426-chloropropionic acid. In each case, after day 0 the relative proportions of these two compounds stayed fairly constant over the duration of the studies, with F8426 at 10-20% of total residues, and F8426-chloropropionic acid at 60-90% of total residues. The estimated half-life for F8426 in the California is 7 days when day 0 data are excluded, which is similar to the half-life for total residues (10 days). The pattern suggests that rather than quickly disappearing, F8426 declines to 10-20% of total residues within one day of being added to water, but thereafter proceeds to decline at a slower rate, similar to the rate of disappearance of the chloropropionic acid degradate.

For these reasons, EFED maintains that the appropriate residue measurement to compare against the 5.9 ppb EC50, in order to establish paddy water holding times, consists of total toxic residues of carfentrazone-ethyl (F8426 plus degradates), and not parent F8426 alone. Most of this is likely to consist of F8426-chloropropionic acid and a smaller percentage of F8426. The lower EC50 for this mixture compared with that of F8426-chloropropionic acid "alone" suggests that the presence of a relatively small percentage of parent substantially enhances the toxicity of this degradate.

Fish Early Life Stage study:

The 18 hour light/6 hour dark cycle was requested in order to try to ascertain whether light has any effect in enhancing the toxicity of F8426 to fish. Given that the test species to be used (rainbow trout) are not ideal subjects for this kind of test (due to the biological requirements of the species they cannot be exposed until they are relatively mature, at the "swim-up" stage), EFED does not feel that 18 hours of daily light exposure instead of 12 hours is an unduly

conservative measure. Depending on latitude and time of year, daylight can be substantially longer than 12 hours. Therefore, EFED prefers that the study be conducted under an 18 hour light/6 hour dark exposure regime.

As previously explained, while F8426-chloropropionic acid constitutes the majority of the total toxic residues of F8426 after day 0, parent F8426 continues to be present at 10-20% of total residues, declining at about the same rate as the total residues. Evidence suggests that the presence of this amount of parent results in enhanced toxicity over the chloropropionic acid degradate by itself. Using applied parent F8426 as the test material more closely approximates conditions in the real world than using applied F8426-chloropropionic acid, because it inherently results in exposure of the test organisms to a mixture of parent and degradates, which is more representative of actual conditions in the environment.

cc: Tom Bloem, HED