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To: Product Manager 16
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Environmental Fate Branch

S. Creeger

Attached please find the environmental fate review of:

Reg./File No.: 476-1713

Chemical: Aspon

Type Product: EUP

Product Name: ASPON 6-E and ASPON 5-GA

Company Name: Stauffer Chemical Company

Submission Purpose: Review of protocol for development of data to support label reentry statements to be proposed by the Registrant.

ZBB Code: _____

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Deferrals To:
_____ Ecological Effects Branch
_____ Residue Chemistry Branch
_____ Toxicology Branch

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REVIEW OF ASPON DISSIPATION PROTOCOL

Introduction: The Stauffer Chemical Company has submitted the attached protocol for studies of dissipation of total and dislodgeable residues of ASPON applied to turf as their 6-E and 5-GA formulations. Their stated purpose is to evaluate potential exposure of humans and pets to these residues. This was in response to a 2/11/81 meeting with the Agency regarding the Registration Standard. It is unclear, however, how data from this study will be used to develop label statements to minimize pesticide exposure.

Discussion: In general, the protocol is acceptable for dissipation studies, but there remains a question of how the residue data will be used to evaluate potential human and animal exposure. There are two ways to resolve the question.

First, the Agency has deemed exposure levels to be allowable if the pesticide residues cannot be detected at the site. If this method is used to estimate an allowable reentry time, the protocol is complete as it stands. However, the Registrant is proposing to determine the residues only for 48 hours, and it is not certain that the residues will dissipate to a non-detectable level by or before that time.

Second, the Registrant could measure exposure levels at two or more times after application (and therefore at two or more residue levels). That data then could be used to relate a residue level to an exposure level. An allowable exposure level can be estimated from no observed effect levels (NOELs) submitted as part of the toxicological data.

Alternative to an exposure study, the Registrant could cite and use data from other exposure studies if such data exist. That data could be from residues on grass or a more hazardous plant/exposure situation. Such data do exist for exposure to tree leaves, which is deemed to be a more hazardous exposure situation. In order to use that data in an exposure evaluation, it would be necessary to have the dislodgeable residue levels in terms of weight per foliar surface area.

Under "6)" in the protocol, there is some confusion about "total" and "dislodgeable" residues. The Agency takes total residue to mean the residue extracted from macerated leaves and takes dislodgeable to mean the residue that can be removed from leaves by shaking in water as outlined in the procedure of Iwata et al. cited by the Registrant. The dislodgeable procedure gives lower residue levels and is appropriate for this type of exposure estimation. It is acceptable for the Registrant to determine these residues on cut leaves as in the protocol. In order to make the dislodgeable residue data most useful, the registrant should report the residue levels

in terms of weight per foliar surface area. That value could be estimated from the weight of the extracted grass by measuring an average foliar surface per unit weight of leaves.

Conclusion: The protocol is acceptable with the suggested change on reporting residue data in terms of weight per foliar surface area.

The Registrant has two possible procedures for utilizing data from this study to prepare an acceptable label. These optional methods are to determine the time for the dislodgeable residues to dissipate to a non-detectable level, or to use toxicity and exposure data to estimate an allowable exposure level and to determine the time necessary for the residues to decline to that value. Thus, this second method would require the Registrant to submit exposure data.

If the Registrant has questions regarding this review, call 703/557-7347.

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