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

Office of Prevention, Pesticides and Toxic Substances

March 10, 2004

MEMORANDUM

SUBJECT: **Naphthalene Acetates**; HED's Response to Public Comment on HED Risk Assessment for Reregistration Eligibility Document (RED) PC Codes:0 56001, 056002, 056003, 056004, 056007, 056008; DP Barcode No: 299298
Reregistration Case 0379

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This provides the Health Effects Division's (HED) response to comments from AMVAC Chemical Corporation on EPA's December 1, 2003 Human Health Risk Assessment for Naphthalene Acetates and its supporting science documents. The risk assessment and supporting documents have also been revised to address AMVAC's comments.

03/04

NAA Risk Assessment Document

Comment: The Agency requests a citrus processing study (for pulp, oil and juice). AMVAC requests a waiver due to the low use rates and the 150 day Post Harvest Intervals.

Response: The Agency can drop the requirement for a processing studies if all field trail data, including one field trial at 5 times the maximum application rate, show non-detectable residues in the raw agricultural commodities. Residue data reflecting the established 150-day PHI are not available. However, detectible residues were found at 0.4 and 1X the maximum application rate at PHIs of 16-24 days. EPA acknowledges that residues would be considerably less at PHIs of 150 days. However, the available data do not provide sufficient basis for waiver of the citrus processing study.

Comment: The toxicology profile on sensitization for acetamide and ethyl ester states that submitted studies are unacceptable because there is no positive control data. There is positive control data in a separate report, an unsubmitted amendment to MRID 4349105 specifically for the ethyl ester but it should also satisfy the acetamide as the time interval is within a few months. This amendment data will be separately submitted.

Response: The toxicology profile is based on available data and cannot be revised based on data that has not been submitted.

Dietary Exposure Assessment Document

Comment: AMVAC believes the Agency is aware IR-4 has generated magnitude of residue (MOR) data on orange, grapefruit and tangerines and thus did not request additional data. IR-4 will be submitting a petition for oranges and tangerines and grapefruit. EPA should include grapefruit in their risk assessment and assign an interim tolerance.

Response: The Agency cannot establish an interim tolerance for grapefruit nor include it in the risk assessment at this time based solely on the registrant's intent to submit the required petition and supporting data.

Toxicology Chapter

Comment: AMVAC requests a waiver from the requirement for a 28 day inhalation study.

Response: EPA agrees to waive the requirement of a 28 day inhalation study because conservatively estimated inhalation MOE's (i.e., MOE's based on an oral toxicity endpoint and an assumption of 100% absorption) are $\geq$ 22,000.

Product Chemistry Document

Comment: The statements regarding potassium salt and ammonium salt products "apparently produced from unregistered TGAIs" is incorrect. Inspection of Confidential Statements of Formula for these products indicates each has a registered source product. For example, the potassium salt products are produced from an NAA technical to which is added KOH as part of the end-use formulation.

Response: The Agency considers the salt, not the acid, to be the TGAI. There is no registered TGAI of the salt.

Residue Chemistry Document

Comment: EPA is requesting storage stability data on apples (or citrus fruits) and olives. The Agency has requested 143 days for apples and 283 days for olives. AMVAC's 1999 studies had data for 109-day freezer storage. AMVAC has consulted with Mike Braverman (at IR-4) and obtained storage stability data for orange (383 days >94% recovery) and tangerine (161 days, >84% recovery). With these citrus storage stability data available, AMVAC understands no additional storage stability data will be necessary for apples and olives.

Response: As stated in the residue chemistry document, adequate storage stability data have been submitted and deemed sufficient for the raw agriculture commodities apples, pears, and olives. However, no storage stability data on the processed commodities of apples (or citrus fruits) and olives are available, and these data are required for registration. The Agency cannot comment on whether the data AMVAC intends to submit is adequate to fulfill this requirement until the data has been submitted and reviewed.

Comment: EPA proposes to revoke the pineapple tolerance since it believes there are no pineapple uses. AMVAC requests retaining this tolerance as an import tolerance to support the developing Central American pineapple market, and is prepared to submit labels with this use. IR-4 has indicated it is prepared to develop supporting data for this use.

Response: The residue chemistry document states that unless AMVAC or other registrants propose uses for the sodium salt of NAA on pineapple and submit supporting data, the established tolerance should be revoked. Given AMVAC's stated intent to support registered uses of the sodium salt and submit supporting data, EPA has revised the document accordingly.

Comment: EPA proposes to revoke quince tolerances since it believes there are no quince uses. Since apples and pear tolerances exist, and quince is in the same crop grouping (pome fruit), AMVAC suggests these tolerances be retained. As the labels are updated, quince uses will be added.

Response: EPA agrees to retain the quince tolerance and will revise the document to include a

crop group tolerance for pome fruit.

Comment: There is no mention of the pomegranate SLN in the residue document. AMVAC presumes this is because it is used only on non-bearing trees.

Response: That is correct.