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

APR 19 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#8E3618. Azinphos-methyl in or on Pomegranates.
Amendment of September 20, 1988.
DEB#: 4505 HED#: 9-0166 MRID#: 405817-01, 407558-01

FROM: Maxie Jo Nelson, Ph.D., Chemist
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C) *mjn*

THRU: Robert S. Quick, Section Head
Tolerance Petition Section I
Dietary Exposure Branch
Health Effects Division (H7509C) *RM*

TO: Hoyt Jamerson, PM Team 43
Registration Support Branch
Registration Division (H7505C)

SUMMARY OF DEFICIENCIES REMAINING TO BE RESOLVED FOR DEB

None.

CONCLUSIONS

1. Since neither a "significant" new tolerance nor a "significant" new food use are involved in this petition, DEB now concludes the data gaps raised by the Registration Standard may be waived for this petition, which involves only a minor use. This action is consistent with current Branch policy.
2. No deficiencies remain germane for DEB for this petition.
3. A copy of this review is being routed to SAOS/SACB/HED for TAS purposes.

RECOMMENDATION

Toxicological considerations permitting, DEB recommends in favor of the establishment of the proposed tolerance (with regional registration limited to CA) of 0.1 ppm for residues of azinphos-methyl in or on pomegranates.

NOTE TO PM: MRID#s 405817-01 and 407558-01 (submitted by Mobay in response to the Registration Standard) are being returned without review.

DETAILED CONSIDERATIONS

BACKGROUND

By transmittal letter dated 9/20/88, the petitioner (IR-4) has submitted their response to our (M. Nelson) review of 5/25/88. DEB's review recommended against establishment of the proposed tolerance (0.1 ppm - pomegranates) because of Registration Standard data gaps in the areas of plant metabolism and product chemistry.

IR-4 has requested the Agency reconsider its position since pomegranates is a low dietary intake crop [51 FR 11341ff, 4/2/86], and the proposed use is not a "significant new use".

DISCUSSION

DEB notes that page 31 (item 2) of the Registration Standard states that 'No significant new tolerances and significant new food uses will be granted until the Agency has received data sufficient to evaluate the dietary exposure to azinphos-methyl.'

As IR-4 has pointed out, neither a "significant" new tolerance nor a "significant" new food use are involved here.

A reexamination of the field trial data [MRID# 405411-01] reviewed by our 5/25/88 memo confirms that no detectable residue (limit of detection, 0.05 ppm) of azinphos-methyl resulted in pomegranates treated via the proposed use directions.

DEB thus concludes the data gaps raised by the Registration Standard may be waived for this petition, which involves only a minor use. This action is consistent with current Branch policy.

No deficiencies remain germane to this petition and the tolerance it proposes.

A copy of this review is being routed to SAOS/SACB/HED for TAS purposes.

cc: M. Nelson, RF, Circ (7), PP#8E3618, TOX-IR, SAOS/SACB/HED
 (R. Tomerlin), ISB/PMSD (E. Eldredge), FDA, R. Schmitt.
 H7509C:DEB:Reviewer(MJN):CM#2:Rm810:557-7423:typist(mjn):
 3618GUTH.POM:4/18/89.
 RDI:SectionHead:RSQuick:4/18/89:ActingBranchSeniorScientist:
 RALoranger:4/18/89.