5/24/83

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAY 24 1983

MEMORANDUM

SUBJECT: PP#2F2728 Iprodione in Almonds
Evaluation of Method Trial for Iprodione and its metabolites in Liver and Milk

FROM: Martin F. Kovacs, Jr., Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: Henry M. Jacoby, Product Manager 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

Results of the method trial for Iprodione and its metabolites in liver and milk have been reported (memo of Mark W. Law, 4/19/83).

Recovery of Iprodione from milk fortified at levels of 0.01 and 0.02 ppm ranged from 92 to 119% (avg. 107%); recovery of the nonhydroxylated metabolite RP32490 from milk fortified at 0.01 and 0.02 ppm ranged from 103 to 112% (avg. 108%) and recovery of the hydroxylated metabolite RP36114 from milk at the same fortification levels ranged from 66 to 75% (avg. 69%).

Recoveries of Iprodione from liver fortified at levels of 0.05 and 0.1 ppm ranged from 76 to 95% (avg 87%); recovery of the nonhydroxylated metabolite RP32490 from liver at the same fortification levels ranged from 85 to 96% (avg. 92%).

With regard to the method trial, the petitioner should be informed of the following changes made in the method:

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1. For nonhydroxylated metabolites and the parent compound, the run temperature for the carbowax column had to be lowered from the 200° - 215°C specified in the method to 185°C in order to separate an impurity causing high control values.

2. Another solvent should be substituted for benzene in the HFBA derivatization step as a safety factor because of the carcinogenic properties of this solvent.

Our Comments/Recommendations

The method sensitivity of 0.005 ppm expressed as iprodione equivalents (Iprodione + RP32490) as claimed by the petitioner in milk (see M. F. Kovacs 10/22/82 memo re PP# 2F2728) was not achieved in the MTO. A method sensitivity of 0.01 ppm was reported for the above two compounds including RP36114 in milk. The high sensitivity levels reported in milk should pose no problems in relation to the proposed 0.02 ppm tolerance for combined residues of Iprodione and its nonhydroxylated and hydroxylated metabolites in milk since metabolism data submitted in conjunction with PP#2F2728 indicated that Iprodione comprised only 6% of the identified 14_C residues (Iprodione + RP32490 + RP36114) which in turn comprised only 65% of the total 14_C residue in milk. The proposed tolerance of 0.02 ppm therefore represents at least 2X the level of method sensitivity for the total toxic residue in milk and >2X the actual level of total toxic residue expected in milk from the proposed use.

We can now conclude that adequate analytical methodology is available for enforcement purposes. TOX and EAB considerations permitting and pending the receipt by RCB of a revised Section F containing the Petitioner's reproposed tolerance expressions under Meat, fat and meat byproducts and milk (see M. F. Kovacs, Jr. 6/16/83 review of 2/23/83 amendment to PP#2F2728) we recommend for the establishment of tolerances for the combined residues of iprodione and its nonhydroxylated metabolites in or on the r.a.c.'s almond nutmeat at 0.05 ppm and almond hulls at 0.25 ppm; for combined residues of iprodione and its nonhydroxylated metabolites in meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep at 0.1 ppm and for combined residues of iprodione and its nonhydroxylated and hydroxylated metabolites in milk at 0.02 ppm.

cc: R.F.
Circu
Reviewer
FDA
TOX
EEB
EAB
PP# No. 2F2728

RDI:Section Head:RSQ:Date:5/10:RDS: Date 5/10/83
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