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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

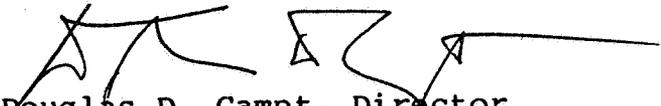
MEMORANDUM

SUBJECT: Policy Group Meeting Agenda
TO: Policy Group Members

There will be a Policy Group meeting Thursday, January 17, from 9 a.m. to 11 a.m. in room 1112. The discussion topics are:

1. Folpet
2. Confidential Statment of Formula call-in project, including discussion of proposed policy on alternate formulations.
3. Labelling Options for Protection of Endangered or Threatened (listed) Species.

Papers discussing items 1 and 2 are attached. Item 3 paper was distributed to Policy Group Members 1/11/85.


Douglas D. Campt, Director
Registration Division

Attachments

Policy Group Members:

- Steve Schatzow
- Susan Sherman
- Anne Lindsay
- OPP Division Directors
- Anne Barton
- Jan Auerbach
- Al Jennings, OPPE
- Peter Preuss, ORD
- Stan Abramson, OGC
- Marion Thompson, OW
- Jim Davis, OPTS
- Peter Jutro, OA
- John Seitz, OCM
- Steve Newburg-Rinn, OTS
- Bob Wayland, OSWER

BRIEFING ON FOLPET ONCOGENICITY

ISSUE

Whether or not to initiate regulatory action and if the decision is to initiate action, what the action should be, for the fungicide folpet. Folpet is oncogenic, mutagenic, and teratogenic based upon studies submitted as part of the Data Call-in.

BASIS FOR CONCERN

The most recent science reviews are attached to this briefing paper.

There is a dose-related increase in the incidence of malignant duodenal adenocarcinoma, a rare type tumor in mice, in the oncogenicity study. Two other studies also raise toxicological concerns. There is a positive teratogenic finding of hydrocephalus in rabbits with only minimal maternal toxicity. There is a positive reverse mutation study in Salmonella that demonstrated that folpet was a direct-acting mutagen (i.e. no metabolic activation required for mutagenicity).

The margin of safety (MOS) for teratology for some common foods based on established tolerances varies between 70.6 and 374.5 for a 60 kg pregnant female. If that person consumed average servings of onion, celery, lettuce, tomato, cucumber, grapefruit, and apple in one day, then the potential dietary intake (based on established tolerances) would be 518.6 microgram/kg/day. Based on the rabbit NOEL of 10 mg/kg/day, the MOS of such a diet would be $10/0.52 = 19.3$.

We do not have a completed oncogenic risk assessment for folpet yet. It was due January 1, 1985. HED - Toxicology Branch has recommended that folpet be considered for special review.

USES AND BENEFITS

It should be noted that folpet is an analog of captan and captafol. Both are presently under special review. These three active ingredients have similar spectra of fungicidal activity. Folpet is more residual but less active. The residual appears to be associated with photodegradation on plant surfaces.

Registered use sites include: The food uses of Apples and Crabapples, Avocado, Blackberries, Blueberries and Huckleberries, Boysenberries, Brambles, Blackberries, Dewberries, Logenberries, and Raspberries, Cherries, Citrus, Cranberries, Currents and Gooseberries, Grapes, Strawberries, Cantaloupe, Celery, Cucumber, Garlic and Onions (dry), Honeydew Melons, Leeks, Onions (green) Shallots, Lettuce, Melons, Muskmelons, Onions, Pumpkins and Squash, Tomatoes, and Watermelons; and the non-food uses for Ornamental Crops of Flowers and Turf grasses and in the formulations of interior and exterior paints.

Established tolerances for residues of folpet in or on raw agricultural commodities are listed under the regulation section 180.191. A copy is attached. One petition for the establishment of a tolerance of 10 ppm in or on kiwifruit (PP 4E3076) is pending. There are no feed additive or feed additive tolerances under 21 CFR 561 and 21 CFR 193 respectively.