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

JAN 25 1984

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Briefing Paper - Folpet

TO: Paul Lapsley, Chief
Special Review Branch
Registration Division (TS-767)

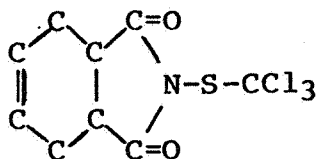
Folpet is scheduled as an early FY 86 Registration Standard (RS). OPP's review to date indicates possible adverse effects. Folpet is a candidate for Special Review (SR). OPP is entertaining options for an interim strategy to handle folpet in light of these adverse effects.

I have provided background information on folpet and its closely related alternatives, captan and captafol because OPP is considering cancellation of captan food and cosmetic uses. The status and recommendations for folpet, as they will be presented to the Policy Group are also discussed.

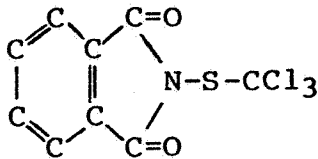
I. BACKGROUND

A. Use

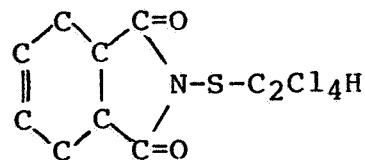
Folpet is a fungicide closely related to captan and captafol. The structure of each is:



CAPTAN



FOLPET



CAPTAFOL

Folpet, captan and captafol have a similar spectra of pests and crops. Folpet is used on fruits, berries, vegetables, flowers and ornamentals. It is also used for plant and seed bed treatment and in paints and plastics. Captan is used on apples, stone fruits, almonds, small fruits, berries, vegetables and ornamentals. It is also used in seed treatment. Captafol is used on apples, cherries, tomatoes, berries, plums, potatoes, citrus, melons and sweet corn. It is also used for seed treatment.

Tolerances for folpet are established under 40 CFR §180.191. Tolerances for captan, established under 40 CFR §180.103, are more numerous than folpet. These tolerances are for pre- and post-harvest application. Interim tolerances have also been established, pending the outcome of the SR. Captafol tolerances, established under 40 CFR §180.267, are less numerous than those of folpet. The tolerances for all three chemicals are summarized in the attached table.

Folpet, captan and captafol are used as wettable powders and dusts. Captafol is also formulated as a granular material. Each chemical can be mixed with insecticides, other fungicides, adjuvants, but not oils or strong alkalis. Folpet is incorporated into paints and plastics, a use which will be discussed later. Folpet is used as a pre-emergent spray, captan as a pre- and post-harvest spray and captafol as a pre-emergent and pre-harvest spray. Only folpet and captan labels currently contain reentry statements requiring protective clothing.

B. Usage

There are 71 folpet registrants with 142 products. The principle manufacturer is Chevron. Approximately 10 percent of folpet in the U.S. is imported. Data indicate that under 3 million pounds were used in 1979, with 86 % of the usage in paint/plastic preservation. Product preservation is a major use because folpet is superior to captan and captafol in photostability. Of the remaining 14 % used in 1979, grapes (8 %), apples (2 %), ornamentals (2 %) and lettuce (0.5 %) accounted for the largest portion of the agricultural uses of folpet. These agricultural uses account for the following percentages of crop treated: onions (16 %), grapes (14 %), melons (14 %) and garlic (10 %). Regionally, the principle agricultural usage is in the northeastern States (grapes), followed by the eastern States (apples) and the pacific States (remaining crops).

There are 142 captan registrants with 619 products. The principle manufacturer is Chevron. Approximately 9 to 11 million pounds annually. Approximate percentages of captan production used on crops are: apples (29 %), peaches (11 %), almonds (9 %), seed soybeans (9 %), strawberries (8 %), seed corn (7 %), seed potatoes (6 %). Regionally, principle usage is in the eastern and central States (apples), nationwide (peaches), California (almonds). Captan is used on a large percent of many treated crops. For example, it is used on 100 % of treated seed corn and 85 % of the strawberries.

There are 3 captafol registrants with 16 products. The principle manufacturer is Chevron. Approximately 4 to 5 million pounds were used annually. Approximate percentages of captafol production on crops are: apples (23 %), cherries (23 %), citrus (19 %), potatoes (11 %) and tomatoes (10 %). The largest percentages of crop treated are: apples (10 %), cherries (25 %), tomatoes (20 %) and plums 15 %). Regionally, principle usage

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lay in the eastern and northcentral States (apples, cherries), Florida (citrus) and the pacific States (potatoes and tomatoes).

II. STATUS

Folpet and captan are two of the original 90 chemicals referred for RPAR review in the Federal Register notice of April 20, 1978. A position document 1 (PD 1) has not been issued to date for folpet. A PD 1 was issued for captan in August, 1980. Captafol was accepted in July 1978 as a referral chemical and a PD 1 was signed on December 19, 1984. Captan and folpet exceeded risk criteria for mutagenicity, teratogenicity and oncogenicity. Captafol exceeds the risk criteria for oncogenic, and acute and chronic fish toxicity effects.

A Data Call-In (DCI) notice was issued for folpet on September 1, 1981. That notice requested the following data and completion dates:

Chronic Feeding (1 species)	9/85
Chronic Feeding (1 species)	10/87
Oncogenicity (1 species)	9/85
Oncogenicity (1 species)	Submitted
Reproduction (1 species)	10/87
Teratology (2 species)	Submitted

A DCI notice will be issued for captan in FY 85. A DCI notice was issued for captafol on September 24, 1981. The requested studies and their status are:

Chronic Feeding (1 species)	Submitted
Oncogenicity (2 species)	Submitted
Reproduction (1 species)	Submitted
Teratology (2 species)	Submitted

A RS for folpet is scheduled for early FY 86. No RS is currently scheduled for captan. The captafol RS was completed on September 28, 1984.

On January 18, 1985, the OPP Policy Group was briefed on the registration status of folpet, captan and captafol. This briefing originated from concerns raised by recent reviews of data submitted as part of a response to a Data Call-In notice on folpet.

Folpet data indicated possible adverse effects in the areas of oncogenicity, mutagenicity and teratogenicity. The teratogenic margins-of-safety (MOS) range from 70 to 375 for single servings, and 20 for single one combination of commodities containing residues at tolerance levels. There are no data to determine the percent of dermal absorption, the presence of adverse male reproductive effects, and data to determine the effect of processing on residues in foods. An oncogenic risk assessment on folpet, originally scheduled for January 1, 1985,

has not been completed to date. Data indicate that folpet causes duodenal adenomas, adenocarcinomas and intestinal mucosal hyperplasia in laboratory animals.

Captan causes duodenal tumors, adenocarcinomas in the digestive tract and kidney tumors of laboratory animals. The oncogenic risk to mixer/loaders is currently estimated from 1.2×10^{-5} to 1.2×10^{-6} . The oncogenic risk to applicators is currently estimated to range from 4.2×10^{-5} to 1.9×10^{-7} . The oncogenic risk to harvestors (strawberry) range from 10^{-4} to 10^{-6} . Total dietary oncogenic risk estimates are 5×10^{-5} . The risks based on residues at the tolerance level, currently range from 10^{-5} to 10^{-9} .

Captafol causes neoplastic liver lesions and lymphosarcomas in laboratory animals. Estimates indicate an oncogenic applicator risk ranging from 10^{-5} to 10^{-7} . Dietary risk estimates, based on residues at the tolerance level, are 2×10^{-4} . Data indicate that spray drift and run-off could lead to contamination exceeding the aquatic LC₅₀ for fish.


III. RECOMMENDATIONS

The following options for folpet (attached) are being considered by the Policy Group:

- o completion of the Standard on schedule,
- o moving the Standard into FY 85,
- o deferring the Standard and initiating a Special Review,
- o issuing a DCI,
- o suspension,
- o rapid changes of labels in the Label Improvement Program (LIP).

I have concurred that the Product Manager (PM) should recommend to the Policy Group that the Standard be completed according to the current schedule. SRB will issue a PD 1, if necessary, at completion of the Standard. I have concurred with the PM on implementation of the proposed LIP for reentry statements and issuance of a DCI notice for the dermal absorption, male reproduction and residue data.

Label improvements, specifying reentry time periods and protective clothing, will protect workers during the RS/SR processes. A DCI request for dermal absorption and male reproductive studies will provide data for both the RS and PD 1, while the crop residue studies will provide data for the PD 2/3.


Michael E. Branagan, Review Manager
Special Review Branch

Attachments

FUNGICIDE TOLERANCES
(ppm)

Commodity	Captan	Folpet	Captafol
Almonds (hulls)	100		
Almonds	2		
Apples	25	25	
Apricots	50		30
Avocados	25	25	
Beans	25		
Beets (greens)	100		
Beets (roots)	2		
Blackberries	25	25	
Blueberries	25	25	35
Boysenberries		25	
Broccoli	2		
Brussel Sprouts	2		
Cabbage	2		
Cantaloupes	25		
Carrots	2		
Cauliflower	2		
Cattle (fat, meat, meat b.p.)	0.05		
Celery	50	50	
Cherries	100	50	50 (sour) 2 (sweet)
Citrus		15	0.5
Collards	2		
Corn	2		0.1
Cottonseed	2		
Crabapples	25	25	
Cranberries	25	25	8
Cucumbers	25	15	2
Currants		25	
Dewberries	25	25	
Eggplants	25		
Garlic	25	15	
Gooseberries		25	
Grapefruit	25		
Grapes	50	25	
Huckleberries		25	
Hogs (fat, meat, meat b.p.)	0.05		
Honeydews	25		
Kale	2		
Leeks	50	50	
Lemons	25		
Lettuce	100	50	
Limes	25		
Loganberries		25	
Macademias			0.1
Mangoes	50		
Melons	25	15	5
Musk	25		

FUNGICIDE TOLERANCES
(ppm)

Commodity	Captan	Folpet	Captafol
Mustard Greens	2		
Nectarines	50		2
Onions (dry)	25	15	0.1
Onions (green)	50	50	
Oranges	25		
Peaches	100		30
Peanuts (hulls)			2
Peanuts (meat)			0.05
Pears	25		
Peas	2		
Peppers	25		
Pimentos	25		
Pineapples	25		0.1
Plums	100		2
Potatoes	25		0.5
Pumpkins	25	15	
Quince	25		
Raspberries	25	25	
Rhubarb	25		
Rutabagas	2		
Shallots	50	50	
Soybeans	2		
Spinach	100		
Squash	25	15	
Strawberries	25	25	
Tangerines	25		
Taro	0.25		0.02
Tomatoes	25	25	15

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PROPOSED REGULATORY ACTION FOR FOLPET

As was decided by the OPP Policy Group a Folpet Work Group was convened on January 22, 1985 to determine alternative regulatory action in response to the toxicology finding that there is a dose-related increase in the incidence of malignant duodenal adenocarcinoma, a rare type of tumor in mice, in an oncogenicity study, a positive teratogenic finding of hydrocephalus in rabbits with only minimal maternal toxicity and a positive reverse mutation study in Salmonella that demonstrated that Folpet was a direct-acting mutagen (i.e. no metaabolic activation was required for mutagenicity). The margin of safety (MOS) for dietary intake was discussed in the "Briefing on Folpet Oncogenicity" paper submitted to the OPP Group on January ;17, 1985. A completed oncogenic risk assessment for Folpet is not yet available.

The alternative regulatory actions considered; by the Folpet Work Group were as follows:

1. Determine the need for making Folpet a "Restricted Use" pesticide chemical after all data reviews have been completed and appropriate risk assessments have been made. The regulatory action would follow the issuance of the Folpet Registration Standard.
2. Place folpet immediately into Special Review and promulgate a PD-1 as soon as possible based on toxicology triggers mentioned in the Brief or others that are available, such as environmental chemistry and fish toxicity.
3. Issue a notice of intent to suspend Folpet products. The final suspension would be based on the risks out weighing the benefits.

RECOMMENDATIONS

Because of the chemical similarity and similarity of toxicological effects of Folpet to Captan and Captafol, the Work Group makes the following recommendations:

1. Impose immediately labeling restrictions to reduce applicator and farmworker exposure identical to those presently required for Captafol. Note, Captafol is post Registration Standard and PD-1.

Folpet labeling would bear the following restrictions:

- a. All end-use products must have the labeling claim under "Direction for Use": "Wear full body clothing and mid-forearm to elbow length chemical resistant gloves during handling and application. Wear a dust mask during mixing and loading.
- b. All end-use products labeled for crop applications must bear the labeling claim under "Direction for Use": "Do not allow persons to enter treated areas within 24 hours following application unless protective clothing is worn. Conspicuously post reentry information at site of application."
- c. For end-use products that bear labeling for use in greenhouses must bear the labeling claim under "Direction for Use": Only the applicator is permitted to be in the greenhouse during application of this product. Open vents of greenhouse during application and at least 1 hour after application.
- d. All products, manufacturing-use and end-use, must bear the following labeling precautionary statements:

WARNING

Causes reversible eye damage. Do not get in eyes, Wear goggles or face shield when handling. Harmful if swallowed or inhaled. Avoid contact with skin and clothing. Remove and separately launder clothing before reuse.

2. Await completion of the registration Standard prior to further regulatory action to reduce applicator and farmworker exposure.
3. Impose immediately the same labeling restriction for capta as spelled-out under 1 above.
4. Because of the commonality of metabolites of folpet, captan and captafol and their similar toxicological effects, an effort to reduce dietary exposure should be made. This should first take the course of reducing tolerance levels for raw agricultural commodities and for food in case of captan. Here such actions as increasing the interval between last application to the time of harvest, cancelling post-harvest uses, and reducing dosages are available for reducing the dietary exposure, short of suspending product uses.

COMPARISON OF FDA AND NATIONAL FOOD PROCESSORS ASSOCIATION (NFPA)RESIDUE DATA ON FOLPET

COMMODITY TOLERANCE		FDA DATA ¹		NFPA DATA	
		No. Tests	(Raw) Residue Levels (ppm)	No. Tests	(Raw) Residue Levels (ppm)
Apples	25 ppm	35 of 1100	.01 - 1.4 ppm	345	N.D.
Carrots	none	-	-	18	N.D.
Citrus	15 ppm	# not given	N.D.	660	N.D.
Potatoes	none	-	N.D.	89	N.D.
Tomatoes	25 ppm	# not given	N.D.	674	N.D.

¹ FDA data represent samples of commercial shipments of raw fruits and vegetables. Monitoring data from 1984-3/9/87 of 2,004 domestic samples of tomatoes, oranges and apples were analyzed.

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COMPARISON OF RISKS FOR FOLPET, CAPTAN AND EBDC

Chemical	DIETARY RISKS		M/L/A RISKS ⁴	
	Oncogenic	Developmental	Oncogenic	Developmental
FOLPET ¹	7×10^{-6}	MOS 33-90	-	MOS 340-47,000
CAPTAN ²	10^{-3} to 10^{-4}	MOS \geq 828	10^{-5} to 10^{-7}	-
EBDCs ³	10^{-5}	MOS 333-556	10^{-5} to 10^{-7}	MOS 87-25,000

¹ Results of a recent TAS report based on FDA and NFPA surveillance residue data and percent of crop treated, indicate an oncogenic dietary risk estimate for folpet of 7×10^{-6} . The previous dietary risk estimate based on 100% tolerance levels and 100% crop treated was 10^{-4} . OPP is requiring residue data on folpet through the Registration Standard.

² Based on the lack of residue data, the dietary risk calculation for captan is based on 100% tolerance levels with 100% crop treated. Residue data on captan have been received and are under review.

³ EBDC dietary risks are based on actual residue data and percent of crop treated (Mancozeb).

⁴ M/L/A risk calculations for folpet, captan and EBDCs are based on dermal absorption rates of 0.4%, 1% and 100%, respectively with no protective clothing/equipment.

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