

SEP 29 1986

MEMORANDUM

SUBJECT: Summary of Folpet Meeting Held September 26, 1986

TO: Team Members (See Below)

FROM: Carol L. Monroe
Review Manager
Special Review Branch

This memo is my summary of the team's discussion on the Special Review of Folpet on September 26, 1983. Please review and comment to make sure we are in agreement as to the outcome of the meeting on the various issues. Please submit your comments to me within a week after receiving this memo.

1. Summary of Risks by Tina Levine

- There are two risk criteria of concern: oncogenicity (based on mouse and rat studies) and teratogenicity (based on a study in rabbits). The oncogenicity presumption is also supported by positive mutagenic studies and by its structural similarity to captan which has been shown to be oncogenic.

- The potential dietary oncogenic risk is of the order of 10^{-4} (captan was 10^{-3}). The highest potential Mixer/Loader/Applicator oncogenic risk is 10^{-4} for application to grapes.

- The dietary teratogenic MOS is 90. The Mixer/Loader/Applicator (M/L/A's) MOS for women of childbearing age is only 1.4.

- It is important to keep in mind that the oncogenic and teratogenic risks for M/L/A's were estimated assuming 100% dermal penetration. It is known that captan has a dermal penetration of 1.3%. This is a low figure because captan is not too soluble in water. Folpet also is not readily soluble in water; thus, the risk figures for M/L/A's are probably conservative.

- It is also important to keep in mind that the dietary risk estimates were based on tolerances which do not have a supporting data base. The Registration Standard, however, asks for residue data. It is likely that those data will indicate that the dietary exposure is not as high as assumed for the current risk assessment.

2. Summary of Benefits by Janet Anderson

- Non-agricultural uses of folpet as a fungicide and mildewcide include paints, stains, and plastics. This use represents \$1.0 million per year. Folpet is only used in oil-based paints because it is not very soluble in water. Alternatives for paints include TBTO and Captan. It is expected that a cancellation of folpet in oil based paints would cause consumers to switch to latex paints.

- For home/garden use, there are alternatives for folpet including benomyl and maneb.

- Agricultural uses represent 200,000 lbs per year usage for grapes, apples, and lettuce. Folpet is effective because it acts in many places in the metabolic pathways of fungi and mildew. Folpet is used for 4 diseases on grapes and is the fungicide of choice for control of the summer diseases in apples. It is used on apples late in the growing season. Without folpet, fruit losses may occur, though a minor economic impact is expected. Maneb is not used on apples because it has a 30-day reentry restriction.

Folpet is used on lettuce in California to prevent downy mildew. Numerous alternatives exist for most uses affecting lettuce and grapes. Insignificant economic effects would be expected if folpet were not available.

3. Regulatory Options Discussed by the Team

a. Cancellation of All or Some Uses

- The Agency could propose cancellation of all food uses of folpet because of the 10^{-4} dietary risk and the MOS for teratogenicity of 90. However, it may be that residue data on folpet will be submitted to the Agency by the time a document proposing cancellation would be ready. At that time OPP could reassess the dietary exposure, based on actual residues, not tolerances. At that time OPP may want to take "percent of crop treated" into account.

- It is unlikely that the Agency would propose cancellation for non-agricultural uses because of lack of data. If data were available, then an exposure and risk estimate would be calculated. We should ask for exposure data in the Registration Standard for applicators who incorporate the pesticide in the paint or plastic and refer the issue to OSHA. OGC indicated the Agency does not have the authority under FIFRA to ask for exposure data for individuals who actually apply the paint, since the paint cannot at that point be called a pesticide. The paint makes no pesticidal claims. However, the Registration Standard should also ask for paint application exposure data and refer the issue to OTS.

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b. Label Changes

- The Registration Standard currently requires the same protective clothing for M/L/A's as captan, namely, elbow-length gloves, boots, overalls with sleeves, a face shield, and goggles. This is expected to reduce the risks for these workers. Joe Reinert indicated the hazard was more acute for Mixers and Loaders than for Applicators.

- Barbara Britton suggested we could propose to have label warnings for oncogenicity and teratogenicity. This would perhaps motivate the M/L/A's to wear the protective clothing.

- The Registration Standard currently lists a reentry restriction of 24 hours for folpet, whereas 4 days was required for captan. The team agreed that we should be consistent with folpet. We will investigate the possibility of a 4 day reentry requirement for folpet. The team supports this 4 day interval because folpet is a B2 oncogen and a teratogen and has a structural similarity to captan.

- The team also proposed a pre-harvest interval be considered for folpet to reduce its dietary risk.

4. Action Items

a. Arvella - Speak with Dave Severn regarding the reentry issue: should folpet have a 4 day reentry restriction as captan does?

b. Janet - Speak with Neil Pelletier about the captan use report: Is there one for folpet?

c. Eugene - Speak with Joe Reinert about EAB's need for exposure data.

d. Carol - Get FDA monitoring report on folpet.
- See EEB about endangered species labeling.
- Check with TOX (Steve Saunders) re the possibility of assuming a 1% dermal absorption for folpet as was assumed for captan.

Team Members Present

Arvella Farmer - SRB
Steve Wolfson - OGC
Cara Jablon - OGC
Eugene Wilson - RD
Barbara Britton - OPPE
Hugh Spitzer - ORD
Janet Anderson - BUD
Don Eckerman - BUD
Jean Lupinacci - BUD
Tina Levine - SIS
Chris Bashore - PFSS
Jim Adams - EAB/HED

Also cc.

Paul Masteradon - EAB/HED
Lynn Bradley - RCB
Dennis McLane - EEB
Phyllis Johnson - BUD
Richard Bright - PCS
Bill Grosse - PMSD
Matt Straus - OSW
Yogi Patel - ODW
Phyllis Flaherty - OCM
Bob Scarberry - OSW
Allan Reiter - EAB/HED