

1/6/94

MEMORANDUM

SUBJECT: Review of Benomyl Data

TO: Kate Bouve, 6a2 Officer
Special Projects and Coordination Staff
Program Management and Support Division (7502C)

FROM: Jerome Blondell, Health Statistician
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THRU: Steve Knott, Section Head
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Please find below, the OREB review of:

DP Barcode: D187815, D187901, D189394, D189837, D190666,
D191359, D192553, D194500, and D194502

Pesticide Chemical Code: 099101

EPA Reg. No.: various

EPA MRID No.: 426493-01, 426885-00, 426886-00, 426879-00,
427178-00, 427441-00, 427632-01, 427943-01,
428664-00, and 428822-00.

I. INTRODUCTION

This memorandum completes the review of the following items related to Benlate 50 DF:

1. D187815 Florida Benlate Inspections
2. D187901 Dupont 1-800 telephone calls
3. D189394 EPA Region Benlate analyses
4. D189837 Lawsuits against Dupont
5. D190666 Lawsuit complaint against Dupont
6. D191359 Dupont 1-800 telephone calls
7. D192553 Benomyl toxicity review from Dupont
8. D194500 Florida review of 28 medical records
9. D194502 Lawsuit complaint against Dupont

II. CONCLUSION

The overwhelming majority of poisoning data and case reports of illness were unaccompanied by any medical documentation. Those cases that were accompanied by some documentation were likely to provide evidence of alternative reasons for the illnesses experienced. None of the cases reported any quantitative information about their exposures to benomyl, only that it had been used. In many of the cases, explanations other than benomyl exposure were found that were just as likely or more likely than benomyl to account for the effects. Although some cases remain unexplained and follow the pattern of illness already reported in Florida (see memorandums from Jerome Blondell to Kate Bouve dated October 14, 1992 and February 18, 1993), none of these reports significantly adds to the evidence that benomyl was a causative agent for the alledged health effects.

III. DETAILED CONSIDERATIONS

1. D187815 Florida Benlate Inspections

This report contains a listing of results of inspections by the Florida Dept. of Agriculture and Consumer Services. All of these inspections involved chemical analysis for benomyl, its metabolites, or contaminants. Inspections were conducted for about 20 nurseries or individuals. In some cases only misuse of pesticides other than benomyl was documented. In only two cases were there detectable levels of pesticides. At Continental Floral Greens, carbendazim was detected in two soil samples at levels of 6 and 31 ppb. At the Fuzzell wholesale Nursery, 5 of 9 analyses of formulated product detected levels of chlorothalonil between 23 and 93 ppm.

2. D187901 Dupont 1-800 telephone calls

Only 2 phone calls were documented in this submission. A male from Hawaii reported that he had sprayed Benlate for 4 and 1/2 years and has shortness of breath which comes and goes and headaches which come and go and he has some bleeding of his gums. An individual's clothing may have been contaminated with benomyl and the individual has developed a rash. However, his doctor told him the rash was probably due to a fungus. Neither of these cases provide sufficient information. The symptoms reported in the first case are consistent with those reported in Florida, but no information is provided on degree of exposure, alternative explanations for the symptoms or time of onset and frequency. Given the likelihood of an alternative diagnosis, the second case can be dismissed.

3. D189394 EPA Region Benlate analyses

EPA Regional Offices were requested to supply results of analyses of Benlate products to the Office of Compliance Monitoring. Possible contaminants were identified on strawberries and in formulated product. These included atrazine (none detected to 62 ppm), captan (1-10 ppm), and vinclozolin (.3-9 ppm). A report on the Fuzzell Nursery found evidence of chlorothalonil contamination. None of these data have been examined by this reviewer for their significance in ascertaining the causes of plant damage. The limited evidence regarding contamination did not provide any substantive evidence regarding the causes of reported human health effects.

4. D189837 Lawsuits against Dupont

One lawsuit by [REDACTED] alleges he "developed a wide range of physical and health related problems" including pain and suffering, personal injury, loss of memory, emotional distress, and increased sensitivity to other chemicals odors and foodstuffs.

In another lawsuit, [REDACTED] alleges she "was injured in her health, strength, and activity, sustaining injury to her body, including but not limited to, eye irritation, chest pains, and a skin rash diagnosed as a chemical burn." Her exposure occurred while playing at a golf course in California.

In another lawsuit, [REDACTED] alleged the same symptoms at the same golf course as a result of exposure playing golf on the same day as [REDACTED].

A fourth lawsuit filed in Puerto Rico has already been reviewed separately. This review is dated February 18, 1993.

A fifth lawsuit was filed by [REDACTED] who allege they "suffered bodily injury and resulting pain and suffering, disability, disfigurement, inconvenience, mental anguish, loss of capacity for the enjoyment of life".

A sixth lawsuit was filed by [REDACTED] and on

behalf of their infant. [REDACTED] was a clerical employee of Dupont's Belle Plant in West Virginia. She allegedly was exposed to "harmful doses of hazardous chemical substances" which resulted in "severe and serious injury to the body and well-being". The exact nature of these injuries is not reported.

A seventh lawsuit filed by [REDACTED] alleges her husband suffered severe damage to his immune system and she suffered humiliation, mental anguish, and emotional and physical distress, and has been injured in mind and body."

An eighth lawsuit was filed by [REDACTED] of Puerto Rico. [REDACTED] operated an avocado tree farm and allegedly suffered bronchitis, pneumonia, asthma, and dermatological sores and rashes as a result of using Benlate.

A ninth lawsuit was filed by [REDACTED] in Alabama. [REDACTED] operated a nursery and claims mental anguish as a result of damage to his crops.

None of the above lawsuits provide sufficient detail or medical documentation regarding exposure or health effects on which to base an assessment of adverse effects of benomyl.

5. D190666 Lawsuit complaint against Dupont

A lawsuit was filed by a nursery worker exposed to Benlate in Florida from 1987 through October 1992. This worker was diagnosed with testicular cancer in June 1992. This case has already been included in the memorandum dated October 14, 1992 which was sent to Kate Bouve from Jerome Blondell. This same memorandum listed two other reports of testicular cancer, neither of which was accompanied by medical documentation.

6. D191359 Dupont 1-800 telephone calls

This letter to Kate Bouve, dated May 4, 1993 contains six reports of phone calls to Dupont concerning benomyl. Three of these calls involved possible health effects. The first was a woman who works spraying benomyl on mushroom beds up to 16 hours a day on weekends. After a weekend she developed symptoms of dry throat and cough and trouble breathing. She has some irritation of the eyes and nose and her doctor thinks she may have an allergic reaction to the mushrooms. A male sprayed Benlate and Scale (another pesticide) for 2 days and developed nausea, vomiting, and abdominal cramps. A woman exposed to Benlate powder over the last 2-3 months developed cold hands, flushed face, a taste in her mouth and difficulty breathing. She also had numbness and tingling in her finger tips. She has had these symptoms before when she was not handling Benlate. When treated at an emergency room recently she was told she was too thin and should eat more. She develops low blood pressure when she stands up.

These cases show evidence of alternative explanations (allergy to mushrooms, effect of other pesticide, and anorexia) that may account for the reported symptoms.

7. D192553 Benomyl toxicity review from Dupont

Copies of the overheads used in the Dupont presentation to EPA in November 1992 are included in this package. Benomyl has been reported to cause skin and eye irritation and skin sensitization.

8. D194500 Florida review of 28 medical records

Florida Dept. of Health and Rehabilitative Services requested medical records from all individuals who participated in their initial survey of September 1992. Of the 55 individuals who had seen a physician 22 submitted medical records. An additional 6 individuals who had not completed the earlier survey also supplied records. Dr. Isabel Stabile, a physician, reviewed these records and found little evidence to support Benlate DF as a likely cause of the individual's health complaints. Medical records were often incomplete or lacking in information about prior history or Benlate exposure. It was very difficult to draw any positive conclusions from these self-reported cases due to lack of any control group. Thirteen cases described symptoms that might well be ascribed to pre-existing disease or alternative diagnoses. Among 6 cases of reported cancer, 3 were considered more likely due to smoking. Eight cases submitted medical records that were too incomplete or illegible to confirm the alleged health effects. Only 1 case was thought to have symptoms possibly related to benomyl exposure. Dr. Stabile notes that the chronic nature of the reported symptoms suggests that stress due to health concern and the financial costs of crop damage may be a major confounding factor. She adds, however, that she would not expect stress to be the sole origin of all the reported health effects in this group. She notes that lack of specificity, consistency and the absence of a dose-response relationship argue against Benlate as being the cause of the reported symptoms.

9. D194502 Lawsuit complaint against Dupont

This lawsuit from [REDACTED] alleges she was exposed to Benlate DF around November 1989 when she was about 5 weeks pregnant. The suit further states that the baby was born with anophthalmia or microphthalmia (being born with no or small eyes). To date this is the only case related to benomyl reported in the United States. A cluster of cases has been reported by the media in Great Britain, which appears to have prompted the [REDACTED] suit which was brought in 1993. The media have also reported two other cases, one in Nicaragua and one in New Zealand. None of these cases are backed up by medical review or documentation.

A study of birth defects in the Columbia floriculture industry examined births among workers. Benomyl was the fifth most common pesticide accounting for 5% of the total use. None

INFORMATION PERTAINING TO PERSONAL PRIVACY HAS BEEN REMOVED

of the 222 birth defects identified were anophthalmia or microphthalmia. The authors concluded that the only birth defect associated with parents exposed to pesticides was birthmarks, specifically hemangiomas. (Scandinavian Journal of Work, Environment, and Health 16:239-46, 1990). It seems unlikely that benomyl is a significant cause of anophthalmia or microphthalmia if it did not turn in a reasonably large cohort of women workers exposed to the product. The individual cases associated with benomyl so far are just as likely to be due to chance or other factors.

cc: chemical file
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