

OCT 21 1999

**MEMORANDUM**

**SUBJECT:**

**FROM:** William R. Schneider, Ph.D.  
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Office of Pesticide Programs

**TO:** Alan Reynolds  
Biopesticides and Pollution Prevention Division (7511C)  
Office of Pesticide Programs

**SUBJECT:** Scientific Assessment of Proposed Label Change for Foray 48F  
Reentry Statement.

Abbott Laboratories has requested permission to delete from their forestry spray labels the statement "Do not enter treated areas without protective clothing until sprays have dried". The formulation contains an isolate of *Bacillus thuringiensis* containing lepidopteran-active Cry toxins. Generally BPPD is concerned about inhalation exposure to high, concentrated, levels of an aerosol of any microbial pesticide, however, the concern for exposure to lower levels of a microbial pesticide is related to its potential for infection, pathogenicity, or toxicity (including the non-microbial components of the formulation). The registered strains of *B. thuringiensis* are not considered to be infective or pathogenic to humans. In acute pulmonary toxicity/ pathogenicity tests, no adverse toxic effects, infectivity, or pathogenicity were seen at doses up to  $2.6 \times 10^7$  spores/kg (*Bacillus thuringiensis* Reregistration Eligibility Decision EPA738-R-98-004, March 1998). Furthermore, an acute inhalation toxicity study in rats (MRID# 43331508) was performed on the formulated product of an almost identical related product, Dipel 6AF, which included all the inert ingredients, and no significant adverse effects were seen. Five male and five female rats were exposed to 5.47mg/l of the product with an average of  $1.44 \times 10^7$  CFUs/l for four hours. No rats died during the study. A few minor, possible, signs of toxicity were gone by day 3 and four females lost weight between days 0 and 7. The acute inhalation LC<sub>50</sub> was calculated to be greater than 5.47mg/l.

The maximum aerial application rate range for all uses is 128 oz/acre which is equivalent to 3788.8ml/A, or for a worst case number, 4 liters/acre. If, in a further worst case assumption, an exposed human were to inhale the entire

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1/2

amount of deposition within a square meter area, there would be 4 liter/acre / 4047 square meters/acre = 0.000988 liters/square meter of exposure. This is less than 1 ml of formulated product.

Given the essentially non-toxic nature of the formulation and the great dilution of the formulation by the time it reaches ground level, there is no scientific reason to believe there could be any adverse effects on humans by an inhalation route of exposure following aerial application of the Foray 48F product. Furthermore, there is no conceivable potential for producing adverse effects on humans of this microbial pesticide via a dermal route of exposure. Therefore, there is no need for the label statement "Do not enter treated areas without protective clothing until sprays have dried" for forestry aerial application. At this time, it may be advisable to retain this statement for the ground application uses of Foray 48F because the exposure from these methods was not evaluated in this assessment. One way to say this might be: "For ground application, do not enter treated areas without protective clothing until sprays have dried." At the time we evaluate all the labels for the RED, this statement can be reevaluated as to whether it should be modified to protect against inhalation of concentrated sprays, possibly by the dust mask method (if the exposure is likely to be that high) and whether dermal protection makes any sense.

2/2