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

MEMORANDUM

OCT 15 1992

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

SUBJECT: SAB Review of Adverse Effects Data to Foray™ 48B, a Bacillus thuringiensis Based Microbial Pest Control Agent (Submission No.: S425001; ID No.: 058998-00007).

TO: Laura Dye/Phil Hutton (PM 17)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: Cindy Schaffer, Microbiologist *CS*
Biological Pesticides Section
Science Analysis Branch
Health Effects Division (H7509C)

ACTION REQUESTED: SAB has been asked to review an adverse effects related incident to Foray™ 48B, a Bacillus thuringiensis var. kurstaki based microbial pest control agent (MPCA) manufactured by Novo Nordisk A/S.

SUMMARY OF REVIEW:

A person with a history of life-threatening food allergies was at home with the windows open on the day Foray 48B was sprayed. This individual was notified of the first day of spraying but unaware of a secondary dose of Bt on the day symptoms occurred. The individual immediately began to have difficult breathing, chest tightness, mouth and throat itching, plugged ears, nasal congestion and horseness. Upper body joint pain and a variety of neurological symptoms occurred within 45 minutes. This person's physician confirmed that these symptoms were typical of previous allergic reactions.

DISCUSSION:

SAB reviewed the component formulation and the material safety data sheets (msds) from Foray 48B. One carbohydrate, [redacted] of the total component formulation, and two preservatives, [redacted] of the total weight, were present in the formulation; nothing unusual was discovered through the msds's. Both this specific carbohydrate and many preservatives have been implicated in food allergies in the past. SAB feels that the organism, Bt, is not the causitive agent in this incident; and therefore suggests that the responsible local authorities continue to notify all potentially affected individuals before Foray 48B is to be sprayed.

INERT INGREDIENT INFORMATION IS NOT INCLUDED