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

MEMORANDUM

27 APR 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: SACB Review of Adverse Effects Data to Foray™ 48B, a Bacillus thuringiensis Based Microbial Pest Control Agent (HED Proj. No.: 2-1827; ID No.: 058998-00007; Caswell No.: 066)

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

FROM: Cindy Schaffer, Microbiologist
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

ACTION REQUESTED: SACB has conducted a review of possible effects to Foray™ 48B, a Bacillus thuringiensis var. kurstaki based microbial pest control agent (MPCA) manufactured by Novo Nordisk A/S. The following review focuses on the possibility of adverse effects related to Foray™ 48B exposure.

NOTE: The following information contains CBI.

SUMMARY OF REVIEW:

A nine-year old boy, [redacted] was exposed to Foray™ 48B as he walked across his lawn approximately 30 - 60 minutes after application of the microbial pest control agent (MPCA). Within five hours, he had a rash over his entire body, was vomiting, had diarrhea, and his temperature was 103°F. After being admitted to the hospital the next day, the hospital laboratory identified a Bacillus species extracted from this patient's blood. A consulting physician acknowledged that these symptoms were indicative of Kawasaki disease. [redacted] was also diagnosed with this disease at the age of 2. This culture was sent to the New Jersey State Department of Health, Division of Public Health and Environmental Labs for further identification. The culture contained a Streptococcus species "contaminant" and a positive identification of Bacillus thuringiensis through the use of the following tests: colony morphology, crystal shape, biochemical tests, crystalline protein profile, immuno-diffusion, and genetic profile. This strain was further compared to Foray™ 48B's production strain, NB 75 by Entotech, Novo Nordisk's biological insecticide group. The strain isolated from this patient was differentiated from NB 75 by the following biochemical testing: NB 75 is able to utilize sucrose and salicin as sole carbon sources while the blood isolate is unable to use these.

FOIA PERSONAL PRIVACY EXEMPT INFORMATION IS NOT INCLUDED

NOTE: Only one blood sample was drawn from [REDACTED] during the period of hospitalization; a minimum of three blood cultures must be performed to confirm these results.

DISCUSSION: Kawasaki syndrome, also known as Mucotaneous Lymph Node Syndrome, is a disease of unknown etiology. Current research is leaning toward the possibility of a relation to Epstein Barr virus, Herpes virus, a Streptococcus species, and rug shampooing, to name a few. The fact that the Public Health Department designated the Streptococcus species as a contaminant in this persons blood may have been a gross error on their part. Numerous studies have shown that a few Streptococcus species have been isolated from other Kawasaki syndrome patient's blood. To date, this is the first illustration of a relationship of Bacillus thuringiensis to this illness. Given the facts that:

1. The strain of Bt isolated from this boy's blood is different than the strain used in the production of Foray™ 48B;
2. A Streptococcus species "contaminant" was found in this patient's blood and was identified in others with Kawasaki syndrome; and
3. Bt has a 30(+) year history as a microbial pest control agent with no other indication of being infectious;

Based on the above information, SACB feels that this episode does not relate to the spraying of Foray™ 48B to the occurrence of Kawasaki syndrome in [REDACTED]

CONCLUSION: SACB does not see a direct correlation of the occurrence of Kawasaki syndrome to the spraying of Foray™ 48B. The registrant should notify the EPA if the symptoms recur; and all further hypersensitivity incidents must be reported to the Agency.

1. T. Tsurumtsu, et.al. A case of Kawasaki's disease combined with septicemia-isolation of Streptococcus sanguis (MCLS-1) and Streptococcus pyogenes from blood at the acute stage. Kansenshogaku Zasshi, 1991, Jan;65(1):124-8.

C.T. Shen, et.al. Reevaluation of Streptococcal infection in the pathogenesis of Kawasaki disease. Acta Paediatr Sin 1990, May-June;31(3):144-50.

T. Akiyama, et.al. Possible role of Streptococcus pyogenes in Mucotaneous Lymph Node Syndrome XI. Immunoelectron Microscopic Observation of Protoplast-like "Spherical Bodies" Detected in Peripheral Blood of MCLS Patients. Acta Paediatr Jpn 1991; 33:292-99.