

US EPA ARCHIVE DOCUMENT

Memorandum

Date: 27 December 1983

Subject: EPA File Symbol: 48598-R INSECTO  
Caswell #734A  
In 11-23-83; record no. 110121 EXPEDITE

From: B. T. Backus  
IRB/TSS

To: Mr. George LaRocca  
Product Manager 15

Applicant: Natural Insecto Products, Inc.  
P.O. Box 11986 221 Sherwood Pl.  
Costa Mesa, CA 92627

Active Ingredient (label declaration):  
Diatomaceous Earth.....90.0%  
Inert Ingredients:.....10.0%

Background:

According to the data matrix the following studies have been submitted for diatomaceous earth: acute oral LD<sub>50</sub> (rat), acute dermal LD<sub>50</sub>, acute inhalation LC<sub>50</sub> (rat), primary eye irritation (rabbit), primary dermal irritation and dermal sensitization.

Comments and Recommendations:

1. An examination of the material received 8-23-83 indicates that none of it adequately addresses short-term toxicity data requirements. The report "Effects of Diatomaceous Earth on Human Health" is primarily a summary of results of inhalation exposure, both involving laboratory animals in experimental settings and humans in epidemiological studies. No information is provided as to particle sizes to which animals were exposed, whether concentrations they were exposed to were actual or nominal, or even numbers of animals that were involved in the studies, so that the material does not even meet the requirements for an acceptable acute inhalation LC<sub>50</sub> study.
2. The short summary "Effects of Ingested Diatomaceous Earth" gives no information as to what actual dosages (in terms of g/kg) subjects received, numbers of subjects etc.
3. The material under the heading "Effects of Diatomaceous Earth on Skin and Eyes" simply indicates that there are no studies in the open literature that the author was aware of.
4. Reference to an exemption from the requirement of a tolerance cannot be used to support a registration. The data used by the Agency to establish a tolerance (or an exemption from the requirement of a tolerance) may have been submitted (and may be owned) by another registrant.

*Byron T Backus* 12-27-83

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