US EPA ARCHIVE DOCUMENT

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MEMORANDUM

DATE: AUG 28 1981

SUBJECT: FAP #IH5303 - Pryethrins, Piperonyl butoxide and diatomaceous earth in Food and Feed Handling Establishments. Amended Registration (#6300-1AA; Perma-guard Household Insecticide D-20).

FROM: D. Ritter, Toxicologist
Review Section #1
Toxicology Branch/HED (TS-769)

OLR 8/27/81
PBJ 8/27/81

TO: G. LaRocca, PM #15
Registration Division (TS-767)

THRU: William Burnam, Acting Chief
Toxicology Branch/HED (TS-769)

WB

Petitioner: International Diatome Industries Ltd.
Yanton, SD

Conclusion:

Toxicology Branch has no objection to extending current clearances of diatomaceous earth to Crack and Crevice Treatment in Food and Feed Handling Establishments pursuant to 21 CFR §193.---.

Discussion:

The petition proposes exempting diatomaceous earth from the requirement of a tolerance when used as an Active Ingredient in a formulation containing pyrethrins-pipyeronyl butoxide. The product is to be used in food and feed handling establishments for Crack and Crevice treatment. Pyrethrins and piperonyl butoxide have been cleared for this use pursuant to 21 §§CFR 193.360 and 390.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Diatomaceous Earth has been exempted as an active ingredient from the requirement of a tolerance for use against insects in stored grains pursuant to 40 CFR 180.1017 and 21 CFR 120.188. It has also been cleared under 180.1001(c), wherein residues of adjuvant materials are exempted from the requirement of tolerance when used in accordance with good agricultural practice as inert (or occassionally active) ingredients in pesticide formulations applied to growing crops or to RACs after harvest.

The inert ingredients are [redacted]

[To our knowledgw there is no formal mechanism for exempting inert ingredients in 21 CFR §193; we defer this matter to RD].

Other Relevant Clearances:

- 21 CFR §182.90 (substances migrating to food from paper and paper board used to package foodstuffs).
- 21 CFR §573.340 (animal feeds as an inert anticaking agent).
- 21 CFR §240.1051 (clarifying agent in fruit juices, drinking water, etc).
- A highly refined material of like composition (SiO_2) is cleared under 21 CFR 172.480 "amorphous silicone dioxide". However, this should not be confused with diatomaceous earth, which, while possessing the same toxicological properties may possess differing physical properties.

Miscellaneous Considerations:

- The label bears restrictions that would remove or cover foodstuffs from potential exposure.
- The label provides that food contact surfaces not be treated.
- Diatomaceous Earth is the major thickening agent in dentifrices, lipsticks and widely used cosmetics, which tends to support a conclusion of safety from the proposed use.

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