MEMORANDUM

SUBJECT: 454-ANS. Comments on the proposed protocol to determine residues in food after applications of microencapsulated chlorpyrifos in food handling establishments. RCB No. 44.

FROM: Linda S. Pogach, Chemist Residue Chemistry Branch Hazard Evaluation Division (72-739)

THRU: Andrew R. Bagman, Section Head Residue Chemistry Branch Hazard Evaluation Division (72-766)

TO: Jay Ellingsen, Product Manager 612 Insecticidal-Oxamnolide Branch Registration Division (72-757)

Nov Chemical Company has submitted for comment a protocol to determine residues of chlorpyrifos in foods following an application of DURBAN NE (NEM-632).

NEM-632 is 11,78 chlorpyrifos - microencapsulated. The registrant did not submit a Confidential Statement of Formula.

Chlorpyrifos (O,O-diethyl O-(3,5,6-trichloro-2-pyridyl)phosphorothioate) may currently be used in food handling establishments in accordance with the following prescribed conditions:

(1) Application shall be limited solely to spot spray and/or crack and crevice treatment in food handling establishments where food and food contact products are held, processed, prepared or served. Contamination of food or food contact surfaces shall be avoided. Food must be removed or covered during treatment.

(2) Spray concentration for spot treatment shall be limited to a maximum of 0.5 percent of the active ingredient by weight. A course, low-pressure spray shall be used to avoid atomization or splashing of the spray.

(3) Paint-on application for spot treatment shall be limited to a maximum of 2 percent of the active ingredient by weight.
(4) Curtail and encroach treatment shall be limited to a maximum of 3 percent of the active ingredient by weight. Equipment capable of delivering a granular or insecticide shall be used.

(5) Application via adhesive strips shall contain a maximum of 10% by weight of the controlled-release product in food-handling establishments where food and food products are held, processed, prepared, or served. A maximum of 35 strips (or 5.15 grams of chlorpyrifos) is to be used per 100 square feet of floor space. The strips are not to be placed in exposed areas where direct contact with food, utensils, and food-contact surfaces would be likely to occur (21 CFR § 193.85).

The registrant proposes to simulate treatment of a food handling establishment, including the treatment of food preparation area, where food is in open containers during the application. 2MC-4822 will be applied using 3 1/3 fl. oz. (0.016) per gallon of spray to the perimeter of a room (9 ft. 6 in. x 12 ft. 7 in.) as a six-inch band spray to the baseboard and as a spot spray to a 2 ft by 2 ft area in the room.

The following samples of food will be in the room and uncovered at the time of treatment: (2) uncooked chicken breasts (200 grams) on a plate, (2) uncooked hamburger patties (200 grams) on a plate, (2) whole oranges on a plate, (2) packages of cooked French fries (200 grams) in a pan, lettuce salad cut up (200 grams) in an open bowl, (2) opened containers (1/2 pt.) of milk set randomly on the table, 200 grams of sliced cheese spread out on a plate, 200 grams of sliced bread (one slice partially covering another) on a plate, (2) small cakes, ready to be served, on a dish on the table.

Control samples will be taken prior to treatment. Four hours after application, triplicate samples of the treated food will be removed from the room and stored in a freezer until analyzed.

All food samples will be analyzed for any possible residues down to a level of 0.01 ppm.

OR CONSIDER

1. Representative raw analytical data and validation data for the analytical method used in determining residues of chlorpyrifos in the samples will be required.

2. Insects in the formulation (including the encapsulating material) must be cleared under title 21 for use in food handling establishments.

3. The regulation as it now stands does not provide for encapsulated materials. A new subsection circumventing the use of encapsulated chlorpyrifos should be added to 21 CFR § 193.85. A position proposing such a new subsection will be voted.

These comments should be forwarded to the registrant.

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