

MAY 24, 1989



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

MAY 24 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Memorandum

Subject: Amended Registration for the Use of Aluminum or Magnesium Phosphide on Psyllium Seeds and Psyllium Seed Husks, EPA Reg. Nos.;

- 40285-2 Degesch Phostoxin® Pellet Prepac
- 40285-8 Degesch Fumi-Cel® and Fumi-Strip®
- 40285-13 Degesch Phostoxin® Prepac Rope
- 40285-14 Degesch Phostoxin® Tablet Prepac

No Accession Number / No MRID Number
DEB Nos. 5128, 5129, 5130, 5131.

From: Jane S. Smith, Chemist
Special Registration Section I
Dietary Exposure Branch
Health Effects Division (H-7509C)

Thru: R. D. Schmitt, Acting Branch Chief
Dietary Exposure Branch
Health Effects Division (H-7509C)

To: J. Kempter PM Team 32
Disinfectants Branch
Registration Division (H-7505C)

Degesch America, Inc. has submitted an application for amended registration of their products, Phostoxin® Pellet Prepac (EPA Reg. No. 40285-2), Prepac Rope (EPA Reg. No. 40285-13), Tablet Prepac (EPA Reg. No. 40285-14), containing 55% aluminum phosphide and Fumi-Cel® and Fumi-Strip® (EPA Reg. No. 40285-8) containing 56% magnesium phosphide. The request is for modification of the label to add psyllium seed and psyllium seed husks intended for drug use under "nonfood commodities which may be fumigated with aluminum or magnesium phosphide".

Psyllium is actually Plantago psyllium whose common name is plantain weed or fleawort. The seeds and seed husks of the plantago psyllium contain natural mucilage and swell into a gelatinous mass when moist. This natural fiber, called psyllium hydrophilic mucilloid, is the active ingredient in Metamucil®, a mild laxative.

Tolerances have been established for residues of the insecticides aluminum phosphide (40 CFR 180.225) and magnesium phosphide (40 CFR 180.375) on a variety of raw agricultural commodities including almonds, barley, oats, peanuts, corn and wheat. No tolerances exist for psyllium seed and psyllium seed husks.

The products are to be used for fumigation against insects which infest stored commodities as follows:

Product	Quantity	Hydrogen Phosphide	Fumigation Space cu. ft.
Phostoxin®	one Prepac	33g	230 to 1650*
Tablet Prepac			
Phostoxin®	one Prepac	1056g	7300 to 52,800**
Prepac Rope	Rope		
Phostoxin®	one Pellet	33g	230 to 1650*
Pellet Prepac	Prepac		
Fumi-Cel®	one	33g	230 to 1650*
Fumi-strip®	one	660g	4600 to 33,000***

* Max dose for nuts, dates, and dried fruits is 825 cu. ft.

** Max dose for nuts, dates, and dried fruits is 26,400 cu. ft.

*** Max dose for nuts, dates, and dried fruits is 16,500 cu. ft.

The temperature, humidity, the tightness and type of structure and the specific pest being controlled determine the period of fumigation and the period of aeration required for effectiveness. These time periods are specified on the label.

According to the Federal Register 21 CFR Part 334, Laxative Drug Products for Over-the-Counter Human Use dated 1/15/85, psyllium seeds and husks are categorized as bulk-forming laxatives. Bran is also in this category. When a product contains a bulk-forming ingredient and claims to be a laxative, the product is subject to regulation as a drug. However, in the absence of laxative claims, e.g. breakfast cereals containing bran, the products are regulated as foods. Like bran, psyllium is a food unless claims are made on the label that it is a laxative e.g. Metamucil®. Psyllium is sold directly in the form of powders, capsules and husks as a food item or supplement (personal contact, Cheryl Dicks, Health Way Foods). When psyllium and bran as food items are labeled such that they are regulated as a drug, the consumption is still in significant quantities unlike most drugs. The FDA considers the oral dose of psyllium for adults to be 2.5 to 30 grams in a single daily dose for indefinite periods of time (Federal Register 21 CFR Part 334).

We do not believe that the destination of the psyllium seeds and husks will necessarily be known at the time of treatment thus ending up in food items rather than as a drug. For this reason, we consider psyllium husks and psyllium seeds as foods.

Therefore, a tolerance is required for the combined residues of aluminum and magnesium phosphide on psyllium seeds and psyllium husks. Alternately, the company may be able to prove to our satisfaction that the destination of the seeds and husks is known at the time of treatment and the label restriction is practical.

Conclusions and Recommendations

We consider psyllium seeds and psyllium husks to be food items that have a drug use. Therefore, a tolerance is required for the combined residues of aluminum and magnesium phosphide on psyllium seeds and psyllium seed husks. Alternately, the company may be able to prove to our satisfaction that the destination of the seeds and husks is known at the time of treatment and the label restriction is practical.

DEB recommends against the amended registration at this time. Either a tolerance should be proposed (along with appropriate supporting data) or information to indicate that restriction against using the products in food or actually exclusively for drugs, is practical.

cc:Aluminum Phosphide & Magnesium Phosphide SF, RF, Circu,
Amended Use S.F., JSmith, RDSchmitt, PMSD/ISB
RDI:ARathman:05/23/89:EZager:05/23/89:RDSchmitt:05/23/89
H-7509C:DEB:JSmith:jss:Rm803a:CM#2:05/23/89