

#358

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Cobley

SUBJECT: TB evaluation of requested registration of new formulation.

DATE: OCT 2 1975

FROM: TB/RD

TO: Product Manager 16,
F.D.R. Gee

Registration No./EPA File Symbol: 538-RGL

Product Name: "Stop Insects Before They Start."

Registrant: O.M. Scott & Sons Co.
Marysville, Ohio
43040

Recommendation:

TB recommends that, providing use of toxicity data from early (before 1967) American Cyanamid pesticide petitions - to which specific references are not made herein - is permissible under the "2(b)" method of support, the formulation be registered after following label changes are made:

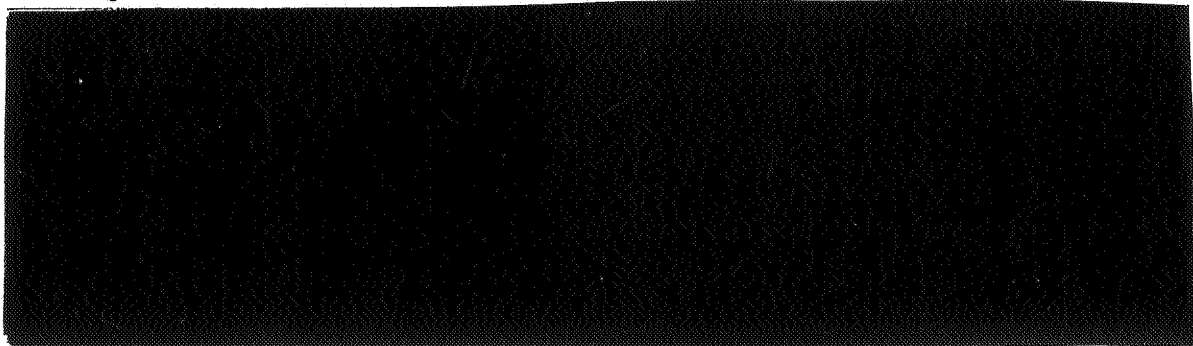
1) Delete all phrases contained in the first paragraph under CAUTION: KEEP OUT OF REACH OF CHILDREN except, "Avoid contamination of feed and food stuffs."

2) Include on label standard phrases, S-76C (Caution: Keep out of reach of children. Avoid contact with skin, eyes, and clothing. First Aid: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes.) and A-42 (Observe all cautions and limitations on labelling of all products used in mixtures.).

Date of Application: 5/14/75; revised 7/7/75 (assigned to Tox. Br. 9/10/75)

Method Support: 2(b), as of 7/7/75 (G.N. Clark, O.M. Scott - F.D.R. Gee, EPA).

Composition of Active Ingredient:

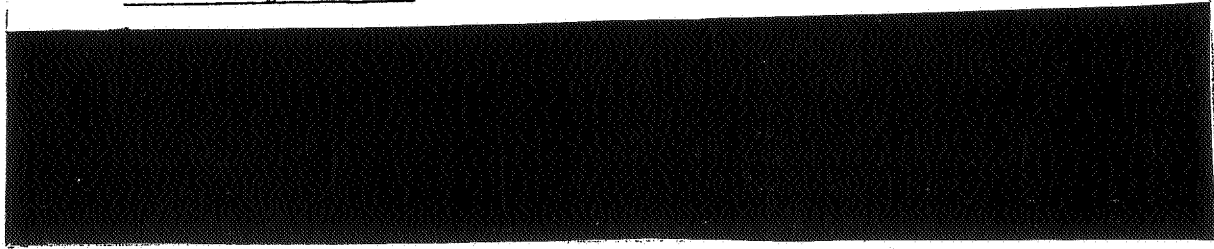


Composition of Formulation:

*0,0-dimethyl S-(N-methylcarbamoylmethyl)
phosphorodithioate*

5.00%

Inert ingredients



Physical State of Formulation: Granules

Toxicity Data.

Toxicity data in the (May, '75) submission consist only of reports on oral and dermal acute toxicity and primary skin and eye irritation of the formulation:

Toxicity data included in this application - from WARF Institute, Madison, Wis., Report of 2/18/75 - on "F-7509, Batch No. 5-23-1-DY, 0,0-dimethyl S-(N-methylcarbamoyl-methyl) phosphorodithioate - 5.5%."

Oral LD50 (rat) = 10 to 20 g/kg BW (Single dose, given to 150- to 250-g, M Sprague-Dawley rats, 6/grp., at 5, 10, or 20 g/kg BW, as dry substance in food jar. Rats, observed for 14 days, thereafter (only), for day of death.)

Dermal LD50 (rabbit, on intact skin) = 8 g/kg BW (Applied to clipped, intact skin of two M adult rabbits at 8 g/kg BW, under rubber "sleeve;" sleeve, removed after 24 hrs and rabbits kept for 2 wks. Both survived, and each gained 100 to 200 g in BW.)

Primary skin irritation index = 0.0 (All readings, Draize, are zero.) (rabbit, on intact and abraded skin) (Applied, "as is," to one each intact and abraded skin site on six albino rabbits; sites, covered for 24 hrs; cover, removed, and sites, scored at 24 and 72 hrs.)

Eye irritation = 6.33 - 24 hrs) Each score, out of a possible 110, (rabbit, "un- 1.0 - 48 hrs) Draize; all corneal and iridic readings washed" eyes) 0.0 - 72 hrs) are zero. (One-tenth g of solid, "as is," placed in one eye of each of six rabbits - other eye, untreated control. Any residue of test material or discharge was flushed from the eye, each time read.)

No toxicity data (i.e., copies of original reports) or specific references to toxicity data in RD or other files on the active ingredient (dimethoate) are included - cf. para. 9 of the "A-2 data exclusivity check list." (There is a letter (A. Bliznick, American Cyanamid - F. D.R. Gee, EPA, 5/8/75) in this submission which authorizes use by RD of Sec.'s C of various pesticide petitions sent in by American Cyanamid.*) Therefore, we are uncertain whether TB can legally complete evaluation of this application under the "2(b)" method of support, and we defer to administrative authority as to this.

* Sec.'s C of PP's Nos. 3F0385, 7F0562, 8F0562, 8F066L, 9G0825, OF0867, OF0928, OF1040, and 1F1087.

In case such toxicologic evaluation is legally permitted, following data on dimethoate, active ingredient (which are abstracted from TB memo of the undersigned in PP No. 3FO385, 5/6/66), are pertinent:

Dimethoate LD50 oral (rat, M) = 245 (185-325) mg/kg BW.

Dimethoate LD50 dermal (rat, M) >> 800 mg/kg BW.

Dimethoate LD50 dermal (guinea pig) > 2 g/kg BW.

"No perceptible irritation or miosis resulted from introduction of ca. 10 mg of (dry) dimethoate into conjunctival sac of rabbit eyes."

In test for delayed neurotoxicity, evidence of demyelination in central or peripheral nervous ~~was~~ ^{was} not seen in hens fed up to 130 ppm dimethoate in the diet for 4 weeks; although positive controls given TOCP did show it. In a similar study, up to 260 ppm of the oxygen analog of dimethoate, fed in the diet to hens for 4 weeks; resulted in no evidence of demyelination.

Evaluation.

We judge above toxicity data sufficient for registration purposes under old (prior to 7/3/75) requirements, providing, it is legally correct to use data from PP's from American Cyanamid, as we have done. PM, please note !

Toxicity data place formulation in (old) Categories IV for acute oral and III for acute dermal toxicity. It is not a skin irritant and is in Category III as eye irritant - pursuant to the J.B. Ritch, Jr. memo of 9/28/74. The granular form and its directed use outdoors make it an unlikely inhalation hazard.

Required signal word is CAUTION. Due to eye irritation, S-76C is called for. Precautionary signal now on label, "Avoid contamination of feed and foodstuffs," is acceptable to this reviewer. Otherwise, the first paragraph under the signal word should be omitted as "overkill." In addition, since label directs use with other pesticides, as standard comment which is proposed for this (A-42) is needed.

MLQ, 10/2/75

Mary L. Quaiife, Ph.D
TB/RD

cc: Branch Reading File

Initial: O.E. Paynter

OFF 10/7/75

MLQuaiife:gac 9/29/75