Shaughnessy #: 128857, 014504

Date Out of EAB: FEB 3 1988

To: Lois Rossi
Product Manager 21
Registration Division (TS 767C)

Accpt

From: Emil Regelman, Supervisory Chemist
Review Section #3
Exposure Assessment Branch/HED (TS 769C)

Thru: Paul F. Schuda, Chief
Exposure Assessment Branch/HED (TS 769C)

Paul F. Schuda

Attached, please find the EAB review of:

Reg./File #: 707-EUP-RRA

Chemical Name: Myclobutanil aka Systhane and Mancozeb aka Dithane

Purpose: fungicide

Date Received: 10/13/87 Action Code: 700

Date Completed: FEB 3 1988 EAB #(s): 80032

Monitoring Study Requested: ___ Total Reviewing Time: 4.0

Monitoring Study Volunteered: __

Deferrals to: ___ Ecological Effects Branch

___ Residue Chemistry Branch

___ Toxicology Branch

1. CHEMICAL:

chemical name:

1) [alpha-butyl-alpha(4-chlorophenyl)-1H-1,2-triazole-1-propanenitrile

2) manganese zinc ethylene bis dithiocarbamate

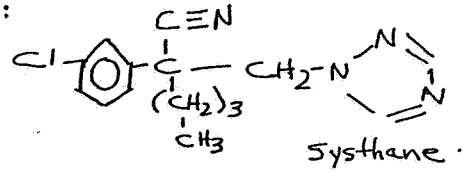
common name:

1) Myclobutanil
2) Mancozeb

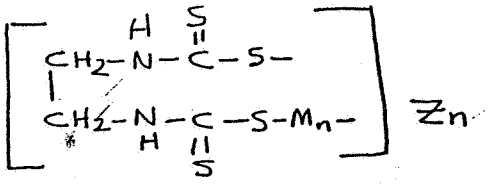
trade name:

1) Systhane
2) Dithane

structures:



Systhane



CAS #s:

1) 66871-89-0
2) 80180-01-7

Shaughnessy #s:

1) 128857
2) 014504

2. TEST MATERIAL: described below

3. STUDY/ACTION TYPE: review of protocol and labelling for EUP on apples

4. STUDY IDENTIFICATION:

Rohm and Haas Company, RH-0611 WP Fungicide (Myclobutanil/Mancozeb) Application for an Experimental Use Permit Use on Apples (Fresh Market Only) EPA Experimental Use Permit No. 707-EUP-[RRA], dated March 1987. Received EPA 04/06/87 under record # 193195.

5. REVIEWED BY:

Typed Name: E. Brinson Conerly
Title: Chemist, Review Section 3
Organization: EAB/HED/OPP

E. Brinson Conerly 2/3/88

6. APPROVED BY:

Typed Name: Emil Regelman
Title: Supervisory Chemist, Review Section 3
Organization: EAB/HED/OPP

FEB 3 1988

7. CONCLUSIONS:

The data requirements for the EUP have not been met for either active ingredient. EAB cannot concur with granting the EUP at this time.

Further, if approval of a protocol is to be obtained, a proper protocol must be submitted. Some (but not necessarily all) of the specific questions which should be answered are as follows:

1. What data from this effort does the applicant intend to develop for submittal to the EAB? It is not clear that any environmental fate data will result from this study, although an orchard field dissipation study, for instance, might fit the submitted description.

Almost any environmental fate field study would require the following information:

2. What are the specific application rates and schedules which will be used, e.g., "We will use six applications of 0.5 lb each at seven day intervals in three test sites, two applications of 2.5 lb each at two-week intervals in four test sites, and one application of 5.0 lbs in six test sites, and maintain ten plots as controls..."If the applicant is unable to be quite so specific, we would suggest a minimum of three dosage levels (high, medium, low), three application schedules (single, med, and maximum) and three growth stages (early, mid, and harvest-ready).

3. How will application rate(s) be confirmed?

4. What is to be the disposition of the treated fruit? Note that without a tolerance for each active ingredient, the fruit must not be marketed.

5. What types of sampling will be done, e.g., soil, fruit, leaves?

6. What intervals of sampling will be used for various types of samples? Note that these should be suitable for various treatment intervals used; for example, if multiple treatment is done, sampling of soil should be done prior to the first treatment,

immediately after each treatment, and at a minimum, once midway between each successive pair of treatments.

8. RECOMMENDATIONS:

The applicant should submit appropriate information to fulfill the data requirements.

The data requirements for myclobutanil which would apply to this EUP and their status per the most recent reviews (JHJ 5/19/87 and EBC 12/17/87) are as follows:

hydrolysis - satisfied
aqueous photolysis - not satisfied
aerobic soil metabolism - additional data are needed re degradates
leaching - additional data required re "aged" compound
adsorption/desorption - satisfied
fish bioaccumulation - data to support a waiver have been received and accepted, and a waiver has been granted

We recognize that mancozeb is presently registered. However, the data base is very incomplete at this time. The data requirements for mancozeb which would apply to this EUP and their status per the registration standard (4/87) and the most recent reviews (CAE 12/8/87 and 8/21/87 are as follows:

hydrolysis - not satisfied
aqueous photolysis - not satisfied
aerobic soil metabolism - not satisfied
leaching - not satisfied
fish bioaccumulation - not satisfied

9. BACKGROUND:

The protocol as submitted is a 14-page document containing the following:

1) a personnel listing
2) qualifications of personnel listed above
3) scope of proposed program
   apple orchards in 23 states
   typical test plots of five acres each
   total acreage = 260
   total a. i. = 520 lb myclobutanil, 13,826.6 lb mancozeb

4) objectives of proposed experimental program

   to confirm product performance when applied in standard grower spray schedules and equipment
   to define optimum use rates, application timing and number of

applications required for disease control and maximum fruit quality
to provide opportunities to define and demonstrate product performance characteristics

5) action plans to achieve objectives of proposed experimental program

foliar application to apples in the listed states with both grower and commercial equipment, with evaluation of disease control, crop tolerance, and crop quality at harvest
treatment at multiple dosage levels from 25 to 50 lb active ingredients/A per season, at stages from dormancy to ripening, and at test sites encompassing a variety of grower management practices, apple cultivars of varying disease susceptibility, and differing climatological conditions
establish demonstration plots at accessible locations and provide tours of these sites

6) duration of experimental permit program
January 1988 to March 1989

7) points of origin of experimental pesticide

8) disposition of containers and unused material
instructions for container disposal will be on the containers, and unused material will be returned to the distribution points for proper disposal

Dosage ranges and treatment schedules are indicated in an (included) proposed label.

A Field dissipation study is currently in for review, but will not materially affect the results of this review.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

The protocol presented contains no specifications which can be approved or disapproved, although the general concepts are acceptable. The ranges of application conditions, rates, and schedules could perhaps be deduced from the label; EAB is unwilling to "second guess" the investigators.

11. COMPLETION OF ONE-LINER: n.a.

12. CBI APPENDIX: n.a.