



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

APR 10 1990

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA # 239-1633. Naled & Trichlorfon. Special
Review Data Call In Requirements. No MRID #.
DEB # 6254.

FROM: Leung Cheng, PhD, Chemist
Special Registration Section II
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Francis Suhre, Section Head
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Brigid Lowery, RM 74
Special Review/Reregistration Division (H7508C)

Dietary Exposure Branch (DEB) has been requested by SRRD to determine the data requirements to fully evaluate the risk of dietary exposure to DDVP resulting from the uses of naled and trichlorfon on food/feed items. The request memo (1/22/90) also states that Special Review Branch is planning to issue a Data Call In notice for naled and trichlorfon later this year.

DEB has been provided lists of required residue chemistry studies for naled and trichlorfon. Each of these will be addressed separately under each chemical.

Naled

171-4 Poultry metabolism study reflecting direct treatment

According to the Naled Registration Standard (6/83), there is a data gap for poultry metabolism. The current label allows direct mist treatments to poultry (except head) with either 3.6 or 7.2 lbs/gal EC formulation at 0.45 lb ai/20 gal. One gallon of treatment solution is to be applied to 100 birds. Metabolism studies on treatment of poultry with naled were not submitted to the Agency (NALED/TRICHLORFON: Potential for metabolism/conversion of naled and trichlorfon to DDVP, F. Suhre, 4/28/88, RCB # 3728, 3729, and 3730).

A metabolism study reflecting direct dermal use on poultry is required.

171-4 Magnitude of residue in meat and eggs from direct application to poultry

The Naled Registration Standard (6/83) concluded that "naled and DDVP residue data are needed in or on eggs and poultry fat and meat byproducts resulting from 10 bird-spray treatments with either 3.6 or 7.2 lb/gal EC ..." (see above cited memo).

Thus, a study to determine residues of naled and DDVP in or on eggs, fat, meat, and meat byproducts of poultry resulting from direct dermal treatment in accordance to label directions is required.

171-4 Processing and cooking studies reflecting actual processing practice

In our (F. Suhre) 5/3/88 memo in connection with a DDVP dietary assessment (RCB # 3718, 3719, and 3720), it was concluded that "Laboratory simulated processing studies are available for tomatoes and oranges; these studies do not reflect actual processing practices."

These studies are required.

171-4 Magnitude of residue - food handling establishment

Residue data reflecting the use of naled in food areas of food handling establishments are required since the label allows such use.

In addition, stability studies reflecting commercial transport and storage of agricultural products are recommended.

In our 5/3/88 memo, we said that stability studies reflecting degradation under commercial transport/storage and refrigerated storage conditions could be utilized in conjunction with data from field residue trials to conduct a dietary exposure assessment for DDVP. DEB continues to recommend that these data be submitted so that more accurate dietary exposure estimates may be obtained.

Trichlorfon

171-4 Livestock metabolism study reflecting direct treatment

The Registration Standard for trichlorfon was issued in June 1984. This Standard required residue chemistry data to support the registered use of trichlorfon as a direct high-pressure spray (80%

SC/S) on beef cattle and as a direct pour-on (8% RTU) application on beef and dairy cattle. No metabolism data are available reflecting direct treatment of beef or dairy cattle, and no adequate residue data are available reflecting direct high pressure spray on beef cattle or direct pour-on application on dairy cattle. The registrant (Mobay) indicated that they would eliminate the high-pressure spray but not the pour-on use from their labels. DEB concluded that metabolism data reflecting direct use on beef cattle must be submitted (Trichlorfon Registration Standard, D. Edwards, 10/24/88).

A livestock metabolism study reflecting direct dermal treatment is required.

171-4 Magnitude of residue in meat and milk - direct application

In DEB's 10/24/88 memo, we also concluded that the registrant must amend the labels to specify a preslaughter interval of ≤ 3 days and provide appropriate residue data reflecting residues in meat, milk, fat, and meat byproducts following such dermal use.

Residue data reflecting such direct application are required.

171-4 Magnitude of residue for DDVP in root crops from soil incorporation

According to plant metabolism studies for wheat, potatoes, and tomatoes, trichlorfon undergoes dehydrochlorination and rearrangement to form DDVP or hydrolysis to form trichloroethanol. DDVP is hydrolyzed to form dichlorovinylethanol which immediately rearranges to dichloroacetaldehyde or dichloroethanol. Thus, DDVP may occur as a residue of trichlorfon in plants grown for food, particularly root crops (beets, sugar beets) on which soil treatment is permitted. Therefore, the registrant must submit data depicting the magnitude of DDVP residues as a result of highest application rate, lowest PHI and maximum number of applications allowed on the label (Followup to the Trichlorfon Registration Standard, D. Edwards, 12/4/87).

Residue data for DDVP in root crops from soil incorporation of trichlorfon are required.

Naled and Trichlorfon

Regarding the product chemistry data requirements for both naled and trichlorfon, data for the certification of DDVP levels as an impurity in TGA1 of naled and TGA1 of trichlorfon are required (Naled Product Chemistry chapter, 10/25/82, and Trichlorfon Guidance Document, 6/30/84).

The other product chemistry data requirement "pH, 8-hr stability after tank mixing per label directions, det. of DDVP in tank mix at t=0, 1/2, 1, 2, and 8 hr - 4 mths for sub. of prot. and for testing (2-3 weeks)" appears to be a requirement for the end use product (EUP). Review of data requirement for EUP is not in the purview of DEB.

Recommendation

DEB recommends that the data gaps discussed above be included in the planned Special Review DCI for naled and trichlorfon.

cc:Circ, RF, Naled Reg Std, Trichlorfon Reg Std, Cheng, FOD/PIB
RDI:FSuhre:4/10/90:RALoranger:4/10/90
H7509C:DEB:CM#2:Rm810:Cheng:3/26/90:1:4/10/90