PP# 7H0576

9-27-74

FAP#4H5046. DDVP premise use. Evaluation of analytical methods and residue data and ltr. of 3/13/74.

SEP 27 1974

Coordination Branch
and Toxicology Branch, RD

The Shell Chemical Company proposes the establishment of a regulation for the food additive 2,2-dichlorvinyl dimethyl phosphate (DDVP) to be used safely for insect control in space, spot and/or crack and crevice treatments of food service, manufacturing and processing establishments including, but not limited to, restaurants, flour mills, supermarkets, and plants handling dairy products, vegetables, oils, candy, macaroni/spaghetti, soft drinks, cake mixes and cookies. To assure safe use of the insecticide, its label and labeling shall conform to the label and labeling registered with the Environmental Protection Agency and the usage employed shall conform with such label and labeling.

Pesticide tolerances for residues of DDVP (Sec. 180.235) have been set for a large number of commodities at levels from 0.02-2 ppm, including all nonperishable packaged or bagged r.a.c.s. Additionally, a food additive regulation has been established for all nonperishable packaged or bagged processed foods at 0.5 ppm.

Conclusions

1. We consider the fate of DDVP from these uses adequately defined and the major terminal residue to be DDVP with DCA as a possible minor component.

2. Adequate methods are available for regulatory purposes.

3a. We conclude that little, if any, residues would result from the use as a space spray or the crack and crevice treatment.

b. A tolerance of 0.5 ppm for perishable commodities is needed in connection with the spot treatment in food service establishments.

c. The data are inadequate for us to determine what residue level will occur from spot treatments in manufacturing establishments or processing plants.

Recommendations

We recommend for the requested regulation as it applies to space and crack and crevice treatments. We recommend against the requested regulation as it applies to spot treatments because of Conclusions 3b and c.

Note: Inerts in the Vaponite E.C. formulation that are not cleared under 180.1001(c) include [redacted] We believe clearance of these inerts should be approved before the establishment of any final regulation.

Detailed Considerations

Formulation

DDVP is manufactured [redacted]

DDVP is to be formulated as Vaponite 2 Emulsifiable Insecticide and Vaponite 2 oil Solution Insecticide. Both formulations contain 2 lbs. DDVP per gallon. Both formulations contain ca. 25% DDVP and related compounds. [redacted] are not cleared under 180.1001(c) for use after harvest. We believe clearance should be approved before any final regulation is established.

Proposed Use

a) Crack and crevice and spot treatment

Apply a small amount of a 0.5% spray directly into cracks and crevices such as expansion joints, between equipment bases and floors, wall voids, hollow equipment legs, conduits, motor housings or junction or switch boxes. The label also notes that any individual spot treatment must be limited to an area of two square feet on which insects are likely to occur. Care should be taken to avoid introducting the material into the air and contamination of food or food processing surfaces. There is no limit on the number of treatments that may be made in any given period of time.

b) Space use

To control small flying insects a 1% solution is applied with fogging or misting equipment at the rate of 1 gallon of the 1% solution per 64,000 cubic feet. Application is to be made when plants are not in operation; occupants are to vacate permises daring treatment and should not reoccupy until the area has been ventilated. All food processing surfaces should be covered during treatments or thoroughly cleaned before using.

Nature of the Residue

The fate of DDVP from the use of Vapona resin strips was discussed in detail in the 2/17/70 review of FAP#OH2477. The uses here would result in the same type of food contamination as the resin strips since food is not directly sprayed but residues may result from volatilization or spray drift. Data available in FAP#OH2477 and also in this petition, show that residue levels in food products are dependent upon the concentration in the air. This concentration in air (as a result of volatilization) varies with the temperature, humidity, ventilation, etc.

As discussed in our review of FAP#7H2166 (J. Wolff, 9/15/67), the major degradation route of DDVP is hydrolytic. In available studies from previous petitions, analyses were performed for residues of dichloroacetaldehyde (DCA), which is a hydrolysis product of DDVP. These analyses show that DCA residues were generally 10%, or less, of the DDVP residue. The possibility exists that all hydrolysis takes place in air; however, because of the large number of samples involved here, we cannot say for certain that decomposition would not occur in any substrate.

Because of the similarity between the uses here and the use of the Vapona resin strips, we would expect maximum residues to result in areas with elevated temperatures and minimal ventilation or in foods with a high fat content.

We consider the fate of DDVP from these uses adequately defined and the major terminal residue to be DDVP with DCA as a possible minor component.

Residue Methods

The proposed method for enforcement is entitled "Residue Determination of Vapona Insecticide in Air, Food, Beverages, Animal Tissues, Eggs and Milk. GLC-Alkali Flame Ionization Detector", method number MMS-R-222-2.

For foods, tissues and eggs the sample is blended, using water, if necessary, to effect a homogeneous puree. An aliquot equivalent to 25 grams of the original sample is shaken vigorously with 100 ml. acetonitrile for 15 minutes. (For liquids and aliquot equivalent to 25 grams is taken and shaken with acetonitrile). The acetonitrile is filtered quantitatively with acetonitrile to exactly 200 ml. An aliquot equivalent to exactly 10 gm of sample is washed twice with 25 ml portions of hexane. The acetonitrile is concentrated to ca. 15ml; 50 ml of hexane is added to the acetonitrile and this solution is concentrated to 10-20 ml. The addition of hexane and concentration is continued until the solvent is completely changed to hexane; the hexane is then concentrated to 5 ml and the solution is

made to 10 ml with ethyl acetate. The residue is then determined by GLC with a cesium bromide flame detector.

No validation data or representative chromatograms have been submitted. Since apparently no data wereggenerated using this method, it is of no concern for our evaluation of the residue data; however, such data would have to be submitted before we could consider this method adequate for regulatory purposes.

The petitioner suggest that method PMS-G-913/69 "Determination of Vapona Insecticide in Agricultural Products GLC Thermionic Emission Detector" be used as a confirmatory procedure. This method was submitted with PP#1F1132 and is a refinement of method PMS-G-913/68 which was discussed in the 4/22/69 and 9/19/69 reviews of PP#9F0788. This method is applicable to foods as well as meat and milk. Additionally, a method for tissues and milk is in the JAOAC 52, 1248-51; 1969. Methods are also available in PAM II. We conclude that adequate method are available for regulatory purposes.
Methods actually used to obtain the residue data include the enzymes inhibitition-spectrophotometric method and several versions of GLC methods using a phosphorus specific Melpar Flame photometric detector. These methods have been discussed in previous evaluations and considered adequate for obtaining residue data.

Residue Data

Most of the submitted studies do not reflect the application of DDVP in actual commercial establishments nor do they reflect application as directed on the proposed labeling. The following controlled studies are applicable to spot use in food service establishments and to space and crack and crevice uses in any food handling establishments.

One study was conducted in motel rooms. Food stuffs were placed on beds and were left exposed during applications. A total of five different types of treatments were madd in this study. The one most reflective of the proposed use consisted of pest control operator (PCO) treatment with a 0.5% solution to baseboards, underneath furniture and window and door sills. The foods that were exposed included apples, applesauce, flour, breads, butter, carrots, corn flakes, hamburger, lettuce, potatoes, sugar and tomatoes. Residue levels ranged from nil (<0.05 ppm) to 0.14 ppm. The 0.14 ppm residue was in butter exposed for 24 hours. An additional test conducted in this study reflecting ca. 2X application rate (a 1% solution) resulted in residues in many more commodities with the residue levels ranging from nil to 0.58 ppm. Both of these tests (and the other tests in this study) are of limited value since the room temperature ranged from 55-60°F. Under these conditions, we would expect air concentrations and residue levels in foods to be lower than at more normal room temperatures.

A study conducted in two homes that reflect a general treatment with a 0.5% solution resulted in residues up to 0.83 ppm in potato chips exposed for 7 hours. Potato chips not directly exposed but in an open bag contained <0.02 ppm DDVP.

A study conducted to simulate treatment in an aircraft with determined air concentrations is available. In this study a low speed wind tunnel was used. A fan adjusted to produce a 5 mph wind which passed over exposed foods and beverages (exposure time of 30 minutes). Coffee, cola, two TV dinners and margarine were the commodities exposed. Air concentrations were varied from a low of 0.035 ug/l to 0.577 ug/l.

The petitioner has noted that air concentrations of ca. 0.1 ug/l could be expected initially as a result of spot treatment, this level would decline to 0.02 ug/l or less in a few hours. Therefore, the above noted studies where the air concentrations were 0.035 ug/l and 0.356 ug/l are in the range that may be reasonably expected from a typical spot treatment. At the 0.035 ug/l level, cola and coffee contained residues in the 0.005-0.007 ppm range, the TV dinners contained a residue of ca 0.04 ppm and the margarine contained ca. 0.16 ppm from the 30 minute exposure. At the 0.256 ug/l level the cola and coffee DDVP levels were 0.02-0.03 ppm, the TV dinners had residues in the range of 0.16-0.19 ppm and the margarine ca. 0.6 ppm.

While the above studies were not conducted in actual food service establishment the data are adequate for us to conclude that residues would only be of significance when food is exposed. Therefore, the space use would result in little, if any, residues since no food would be exposed. For crack and crevice treatments, the minute quantities of pesticide and the mode of application (introduction directly into the crack or crevice) precludes the possibility of any significant contamination of foods. Additionally, the data would tend to reflect an exaggerated exposure in food service establishments and indicate a need for a food additive tolerance of 0.5 ppm to cover residues in perishable commodities.

There are established DDVP tolerance for a number of r.a.c.'s and for non-perishable commodities. The possibility exists for an additive residue effect from these established tolerances in conjuction with the presently proposed uses. However, we believe the additive effect from the established tolerances would be minimal in light of the labile nature of DDVP.

Many studies using the Vapona resin strips are available in FAP#OH2477 and were discussed in detail in the many reviews of that petition. While these studies are not directly applicable to the uses requested in this petition, they do show that residues will result in exposed foods from DDVP residues in the air. It should also be noted that all of the above discussed studies are primarily reflective of use in food service establishments (restaurants,

groceries etc.) and do not reflect use in manufacturing establishments or processing plants.

To support the use in the types of establishment mentioned above, the petitioner has submitted some reports of FDA sample analyses. One involves samples taken from a plant producing spaghetti. The plant had been treated with DDVP on monthly intervals over 2 years. No DDVP residues were detected in any of the sampled products. Additionally, a Food & Drug Administration computer print out for samples analyzed by FDA for DDVP was submitted. This printout indicates two samples from Detroit district were analyzed for DDVP in FY'73 and contained trace residues.

Neither of these FDA reports reflect a controlled testing of DDVP in food establishments. We do not consider these reports an adequate showing of the residue levels that many result in manufacturing establishments or processing plants. Therefore, data from these types of operations should be submitted.

Concerning the data reflecting food service establishments, the available information indicates that residues of up to 0.5 ppm may result in some food items that are likely to be exposed. The petitioner contents that already established pesticide and food additive tolerances are adequate to cover these residues. However, many of these commodities are perishable, and the present tolerances are either not high enough or not applicable. We believe that a tolerance of 0.5 ppm in perishable commodities needs to be requested in connection with the use in food service establishments.

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