State of California
Memorandum

HSM-95003
(HSM no. assigned after memo original issuance)

To: John M. Donahue, Chief
Worker Health and Safety Branch

Date: November 30, 1995

Place: Sacramento

phone: 445-4263

From: **Department of Pesticide Regulation** - Michael H. Dong, Staff Toxicologist
Worker Health and Safety Branch

Subject: Label Amendments Proposed by Valent USA for Use of Danitol™ 2.4EC Spray (Fenpropathrin) on Tomatoes and Strawberries.

A mini risk assessment was presented recently by Valent USA (in DPR Registration Document Volume 50489-150) for the additional use of their Danitol™ 2.4EC Spray (fenpropathrin; EPA Reg. No. 59639-77) insecticide/miticide on tomatoes and strawberries. The conclusion from a preliminary review of this mini risk assessment is that even though the assessment results may be utilized to support the subject product's use on tomatoes, they certainly *cannot* be so utilized for strawberries.

The fenpropathrin dislodgeable foliar residues (DFR) calculated by Valent was nearly 0.5 $\mu g/cm^2$ for the fourth day (i.e., first day after PHI = 3 days) after three successive applications were made to the same *tomato* field. Contrary to their claim, the calculation of this DFR estimate was *not* based on the upper 95 percentile prediction limits; instead, it was calculated straightly from the regression line *per se*. At any rate, the use of this lower, *curve-fit* DFR estimate is deemed appropriate here, in that a seasonal *average* daily dosage is to be used for calculating the MOS (margin of safety) in question. Based on this DFR estimate, on the NOEL (no observed effect level) of 3,000 μg/kg BW/day determined by the Medical Toxicology Branch, and on a dermal transfer factor (TF) of 1,150 (μg/hr per $\mu g/cm^2$ DFR) previously used by this Branch for harvesters wearing a short-sleeved shirt without gloves, the MOS calculated by Valent was 170. According to the (proposed) amended label, reapplication interval for tomatoes is 7 days (and hence as many as three successive applications were considered here).

The DFR calculated by Valent was nearly 0.7 $\mu g/cm^2$ for the third day (i.e., first day after PHI = 2 days) after a single application was made to the *strawberry* field. Based on this (*curve-fit*) DFR estimate and on the same NOEL and TF used above, the MOS calculated by Valent was 120. However, there is no evidence that the same transfer factor of 1,150 used for tomato harvesters could be used for strawberry harvesters. (Reapplication interval for strawberries is 30 days.)

The vast majority of the literature data on hand do not support a potential dermal (i.e., an apparent) TF lower than 3,000 or 4,000 for strawberry harvesters. It is mathematically evident that even with a TF of 2,000, the MOS of 120 calculated by Valent for strawberry harvesters would be reduced nearly two-fold, much below 100.

The (six) TF observed by Krieger *et al*. [1] from several field studies averaged 4,750. This TF average is about two times *lower* than that calculated from still several other field studies included

in Zweig *et al*. [2] (after adjustment for two sides of leaf surface). The pesticides used in all these studies included carbaryl, captan, malathion, dicofol, and naled.

For workers *wearing gloves* while picking strawberries treated with captan, the apparent TF was determined by Maddy *et al*. [3] to be between 250 and 650. Their data further indicated that hand exposure accounted for 50% (or more) of the total dermal exposure measured, with gloves (of their type) having a clothing protection of more than 38-fold. Therefore, for workers picking (captan-treated) strawberries *without* gloves, the midpoint TF in the range observed by Maddy *et al*. should be increased to about 9,000. Even if a default factor of 10-fold were used for glove protection, the midpoint TF observed in Maddy *et al*. would still be increased to about 2,500. The midpoint TF calculated here for workers picking (captan-treated) strawberries without gloves should be increased even more, had the study subjects worn the union suit (long underwear) with short sleeves, instead of long sleeves, as the dermal dosimeter.

Edmiston *et al*. [4] and Saiz [5] on the other hand both found that the apparent TF could be as low as 2,000 for strawberry harvesters (after proper adjustment for total body exposure, etc.). However, the captan exposure data as well as the clothing scenarios presented in their poster paper or review memorandum were not adequately described to make full use of the much lower TF estimated by these investigators. For instance, the dermal dosimeter used in the field study described by Saiz was only a long-sleeved cotton Tee-shirt. However, it is not clear if this Tee-shirt was actually worn underneath a jacket, or if some harvesters actually rolled up their sleeves while they were working in the strawberry field.

Finally, even though the MOS of 170 calculated by Valent for tomato harvesters appeared to be adequate, this (risk) estimate was based on a dermal TF of 1,150 derived primarily for e*mergency* exemption registration purposes without the benefit of allowing a more extensive, time-consuming literature search. Exposure data used for the derivation were from a single study in which daily exposure was monitored for workers harvesting *bush* tomatoes treated with chlorothalonil. These exposure data, together with the chlorothalonil DFR that were also measured in that study, were made available in the exposure assessment for chlorothalonil [6]. The TF estimate derived from these two sets of data continues to retain the same practical value (1,125) in the recently revised exposure assessment draft document for chlorothalonil, as long as its surrogate use is meant for bush tomato harvesters wearing a *long*- (vs. short-) sleeved shirt without gloves. The same revised draft chlorothalonil document also indicated that the dermal TF was 1,400 for workers harvesting *pole* tomatoes treated with chlorothalonil while wearing a *long*-sleeved shirt without gloves. Note that in practice the apparent and the actual dermal TF should be nearly the same for tomato harvesters wearing *a short-sleeved shirt without gloves*, since their (fore)arm and hand exposures together would account for as much as 70 to 90% of the total dermal exposure.

<u>Recommendation</u>
Based on the above considerations and more recent observations, it is thus recommended that the label for Danitol 2.4EC Spray be further amended to specify that both tomato and strawberry harvesters wear gloves and a long-sleeved shirt, as well as long pants and shoes plus socks.

References

1. Krieger R, Blewett C, Edmiston S, Fong H, Gibbons D, Meinders D, O'Connell L, Ross J, Schneider F, Spencer J, Thongsinthusak T (1990). Gauging Pesticide Exposure of Handlers (Mixer/Loaders/Applicators) and Harvesters in California Agriculture. *La medicina del lavoro* 81:474-479.

2. Zweig G, Gao R, Witt JM, Popendorf W, Bogen K (1984). Dermal Exposure to Carbaryl by Strawberry Harvesters. *J Agric Food Chem* 32:1232-1236.

3. Maddy KT, Krieger RI, O'Connell L, Bisbiglia M, Margetich S (1989). Use of Biological Monitoring Data from Pesticide Users in Making Pesticide Regulatory Decisions in California: Study of Captan Exposure of Strawberry Pickers. In *Biological Monitoring for Pesticide Exposure: Measurement, Estimation, and Risk Reduction*; Wang RGM, Franklin CA, Honeycutt RC, Reinert JC, Eds.; ACS Symposium Series 382, American Chemical Society, Washington, DC.

4. Edmiston S, O'Connell L, Blewett C, Schneider F, Spencer J, Krieger RI (1990). Dislodgeable Foliar Residues Can Be Used To Predict Exposure Potential for Work Tasks. HS-1632. Worker Health and Safety Branch, California Department of Pesticide Regulation.

5. Saiz S (1990). Review Memo: Captan Transfer Factor Calculations Based on Strawberry Harvester Data. Worker Health and Safety Branch, California Department of Pesticide Regulation, dated 02/06.

6. Thongsinthusak T, Blewett TG, Ross JH, Krieger RI (1991). Human Exposure Assessment for Chlorothalonil. HS-1475. Worker Health and Safety Branch, California Department of Pesticide Regulation.

cc John Ross
Tom Thongsinthusak