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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Subject: Worker Risk Characterization for the Use of Fenbuconazole in/on Bananas and Pecans. (Indar 2F Reg. No. 707-231).

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Background and Toxicology Endpoints

The need for a risk characterization for bananas and pecans was required based on the outcomes of the Less-than-Life Time Committee (LTL) and Cancer Peer Review Committee (CPRC) meetings. The toxicological endpoints identified by the LTL for short and intermediate term occupational and residential exposure were respectively, developmental toxicity (rat; 60 mg/kg/day) and, separately,liver toxicity (rat; 5.1mg/kg/day) in a 90-day oral feeding toxicity study.
The LTL also confirmed a dermal absorbtion factor of 12.35% The CPRC concluded that fenbuconazole was a carcinogen and that a low-dose extrapolation model be applied to the experimental animal tumor data for quantification of human risk (Q* equals 1.65 x 10-2 mg/kg/day).

Bananas - Worker Risk Characterization

The life time cancer risk to workers[mixers + loaders (open pour) + applicators (open cab)] from exposure to Indar 2F using air-blast ground equipment to spray bananas was calculated to be 2.16x 10-7 based on a lifetime average daily dose of 6.208 x 10-7 mg/kg/day for mixers plus loaders (M/L)and 1.248 x 10-5 mg/kg/day for applicators(A). The dermal absorbtion value of 12.35% was utilized in determining the amount of active ingredient absorbed

systemically by the dermal route and the original OREB exposure values were adjusted accordingly. Absorbtion from exposure by the inhalation route was assumed to be 100%.

Margins of Exposure (MOE) for M/L/A using air blast ground equipment in spraying bananas from short term (daily exposure) and intermediate term (average daily exposure) were greater than 40,000 for developmental effects and greater than 190,000 for liver effects respectively. The original OREB values for dermal exposure were adjusted for a dermal absorbtion value of 12.35 percent.

OREB has, however, indicated that they do not have adequate exposure data for M/L/A using backpack spray equipment when applying fenbuconazole to bananas. However, in discussions with OREB personnel (personal communication with Art Scholsser, Steve Knott and Al Nielsen; November 15, 1994) there was a basis for agreeing that in general the application of fenbuconazole using backpack equipment [which is considered a high exposure scenario] could be in the general range of the exposure values obtained from ground air blast application for bananas. The MOE for backpack use would therefore appear to be adequate in protecting workers who mix, load and apply the pesticide particularly with the currently calculated very large margins-of-exposure for air blast equipment. The lifetime cancer risk value of 2.16 x 10-7 obtained from exposure values generated by ground air blast equipment might also be considered adequate for backpack users (M/L/A) spraying bananas. However, it is re-emphasized here that exposure data for applicators and mixer/loaders working with backpack spray equipment is lacking for fenbuconazole when used on bananas and lacking generally in the OREB Pesticide Handlers Exposure Data (PHED) base. The values obtained from ground air blast equipment for bananas and applied to workers using backpacks are considered to be only generally reasonable gross estimates in the absence of actual backpack exposure data for this use. It is therefore recommended that the registrant be required to generate the appropriate exposure data within a reasonable period of time (ie. the next use season) under the label use conditions for Indar 2F on bananas as a condition of registration.

Pecans - Worker Risk Characterization

MOEs for M/L/A from the application of Indar 2F to pecans by air blast application under the specified use conditions were 30,0000 or greater for both short and intermediate term exposure. Margins -of-exposure for M/L/A from the use of Indar 2F when applied aerially to pecans was greater than 100,000 for both short and intermediate term exposure.

The lifetime cancer risk to mixers/loaders and applicators from exposure to Indar 2F for use on pecans using ground application air blast equipment was calculated to be 2.76 x 10-7 and for fixed wing air application 6.01 x 10-8 under use conditions.

Conclusion: Margins-of-exposure for mixers, loaders and applicators from short and intermediate term use for the use of Indar 2F on bananas or pecans using air blast equipment or backpack sprayers on bananas, or aerial application to pecans are all greater than 30,000. The lifetime cancer risk for the above uses for M/L/A range from 2.16 x 10-7 to 6.01 x 10-8.

Recommendation:

It is recommended here that worker exposure data in the use of backpack spray equipment be generated by the registrant as a condition of registration and be provided to the Agency within a reasonable period of time (ie. the next use season). Exposure data from this use is currently lacking.

NOTE: Individual risk numbers and calculations have been incorporated directly onto the individual OREB review memos for bananas and pecans and are attached.

Attachments.