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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: TPTH: Response to EPA Transmittal of the Preliminary HED and EFED Risk Assessments [for TPTH, PC Code # 083601] dated June 30, 1999

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Responses to the HED and EFED TPTH Preliminary Risk Assessment, dated June 30, 1999, were received from Landis International consultants in their memo on behalf of the TPTH Task Force. The comments received were summarized in the Landis memos dated August 26, 1999.

In summary, HED has not received any additional data from the registrant that would alter the occupational exposure assessment dated May 6, 1999. However, the assessment has since been revised to incorporate a more robust unit exposure value for mixing/loading wettable powder in water-soluble bags (WSB). This revised unit exposure value was calculated from the combined data from PHED's WSB scenario and the chemical-specific study for WSB. The unit exposure value in the previous assessment was based solely on the chemical-specific study data.

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Toxicology

The Task Force's response disagrees with the endpoint selected for the assessment, however, there seems to be a misunderstanding concerning which endpoint was employed. An acute toxicity endpoint, based on maternal effects in an oral developmental study, was not used in this occupational exposure assessment. The short- and intermediate-term dermal endpoints, which were determined from a special dermal developmental toxicity study, are based on no observed adverse effects (maternal or developmental) at the highest dose tested. This should be protective of both sexes. The likelihood exists that women (potentially pregnant) will perform mixing/loading or applying activities; therefore, it would be inappropriate to target an endpoint that is only protective of males.

WSB study

The chemical-specific study that was submitted by the TPTH Task Force yielded a unit exposure value of 0.046 mg/lb ai. The activities that were monitored in the study were mixing/loading water-soluble bags (WSB) in support of application to pecans with an airblast sprayer. This study was designed such that each replicate represented the mixing/loading of only enough WSB formulation to treat 5 acres at a time. Thus, this study resulted in a unit exposure that is not optimal for assessing exposures from mixing/loading a quantity of WSB large enough to treat 150 acres (groundboom sprayer) or 1000 acres (aerial sprayer) per day.

As an alternative method of deriving a unit exposure, the study data were combined with PHED's non chemical-specific data for mixing/loading WSB, which resulted in a unit exposure value of (0.022 mg/lb ai). The occupational and residential exposure assessment has been revised to reflect this (see revised Occupational and Residential Exposure Assessment, September 14, 1999, K. O'Rourke). Please note that this technique was not used in the previous assessment, dated May 6, 1999, because at the time PHED v1.1 did not have the capability of exporting the raw data to spreadsheets, and MRID# 43599401 did not have a signed data waiver for incorporation into PHED. Now that the PHED data has been merged with the TPTH study data, the MOEs for the combined data set for mixing/loading of wettable powder in WSB for aerial/chemigation application range from 33 to 82. Again, the combined data set is extrapolated to the large quantity of TPTH needed to treat the high-acreage crops (i.e., sugarbeets and potatoes).

The Task Force's response discusses the possibility that the high exposures observed in the study are unique to mixing/loading WSB for airblast. Landis stated that exposure resulted from the physical contact of garments with the spray tank that had been covered with residues from the previously sprayed batch. HED does not agree with this statement because groundboom and aerial spray tanks also receive overspray and require contact during refilling. In addition, the study showed that detectable residues were primarily on the hands (beneath chemical-resistant gloves) and some on the thighs, indicating that exposure occurs regardless of whether the handler's garments contact the equipment's reservoirs after overspray has been deposited.

It is the Agency's intent to encourage the development and use of engineering controls, including water-soluble packaging. However, assurance is needed that the mixing/loading of large quantities of WSB does not contribute the magnitude of exposure that was estimated by extrapolation of the study data. Therefore, an additional study is requested to support mixing/loading WSB for groundboom and aerial/chemigation application. This study should be adequately designed to reflect the large acreage that may be treated with groundboom or aerial/chemigation equipment. Alternatively, label restrictions could be set that permit the use of WSB for airblast application only, while groundboom and aerial/chemigation could require closed mixing/loading systems.

Unit exposure values for baseline, PPE, and engineering controls

The Task Force's response expresses concern that the unit exposure values for airblast and groundboom application scenarios do not have appropriate protection factors applied when progressing from baseline to PPE or engineering controls. It is the policy of HED not to rely on protection factors when actual data for each scenario are available. Protection factors are only recommended when there are no data to represent a specific need. In the cases of airblast and groundboom application, PHED affords applicable unit exposure values for baseline, additional PPE (except that a 50% protection factor was necessary to represent a double layer of clothing), and enclosed cab. Therefore, the protection factors mentioned in the Task Force's response are not applicable.

Mixing/loading using "closed systems" vs. WSB

There seems to be a misunderstanding concerning the exposure assessment of the flowable formulation of TPTH. The Agency intended to communicate that there is potentially less exposure from closed (not open) mixing/loading systems than from mixing/loading using water-soluble bags. The open-pour method of mixing/loading the flowable formulation would be expected to contribute significantly more to dermal exposure than either the closed system or WSB.