

US EPA ARCHIVE DOCUMENT

Note: Bill Burnam

From: Steve Dapson  
Curt Lunchick

*Stephen C. Dapson 2/28/90*  
*Curt Lunchick 28 February 90*

Re: Proposed HED DCI for Diphenylamine

We wanted to take this opportunity to appraise you of our decisions on diphenylamine and what HED will require to complete a risk assessment for this chemical.

The assessment of non-dietary risk from the airblast application of diphenylamine is awaiting the use assessment from BAB/BEAD. Dennis Szuhay of BAB has stated that nobody uses diphenylamine by airblast. This use appears to have ceased about 15 years ago. BAB is providing NDEB with an airblast use estimate based on existing label directions and typical airblast use parameters. Once this data is obtained, NDEB will be able to provide direct exposure estimates to diphenylamine and the contaminants present in the formulations based on someone deciding to use the airblast application.

Data are needed to assess the metabolic fate of diphenylamine in mammals. These data would be used to estimate in vivo conversion of the parent compound to N-Nitroso-Diphenylamine. In addition it would also be used to permit the calculation of worker dosage to diphenylamine and its substituents based on worker urine data.

Non-dietary exposure data are required for the post-harvest uses of diphenylamine. This will require biomonitoring studies. It is recommended that HED request that SRRD issue a DCI for these studies and that the DCI be issued by April 1990 so that the registrants can be required to obtain the data this use season which would be September - October probably. Time is of essence here. The registrant would have to monitor the workers' urine for diphenylamine, N-nitroso-diphenylamine, 4-aminobiphenyl, and 2-aminobiphenyl. Concurrent with the registrant monitoring of worker exposure, it is recommended that OPP pursue collection of the data in conjunction with CDFA and EMSL-Las Vegas. This would provide us with insurance in obtaining the data in case the registrant has an "inadvertant" delay and misses the 1990 use season. Missing the use season would delay a data-based regulatory action by one year. EMSL is requesting \$20,000 to help us and a decision is needed as to whether we are going to pay up. CDFA is not charging OPP for their efforts.

Recommendation: HED request that SRRD issue a 3(c)2(b) for the following studies:

1) Post-Harvest Worker Biological Monitoring study. Workers handling apples treated by dipping, spraying on roller sorters, and drenching would be monitored. Workers involved anywhere from the addition of diphenylamine to the application equipment to the time treated apples are placed in storage would be monitored including those workers draining and cleaning the application equipment. The workers' urine would be analyzed for diphenylamine, N-nitroso-diphenylamine, 4-aminobiphenyl, and 2-aminobiphenyl.

The following data is necessary for a complete evaluation of the potential human toxicity of diphenylamine by the TB-HFAS:

<b>Guideline #:</b>	<b>Description:</b>
81-3	Acute inhal. tox-rat
81-6	Dermal sensitization
82-1(a)	90-day feeding-rodent
82-1(b)	90-day feeding-nonrodent
82-2	21-day dermal-rabbit/rat
83-1(a)	Chronic tox-rodent
83-1(b)	Chronic tox-non-rodent
83-2(a)	Oncogenicity-rat
83-2(b)	Oncogenicity-mouse
83-3(a)	Teratogenicity-rat
83-4	2-generation repro-rat
84-2(a)	Gene mutation-ames
84-2(b)	Struct.chrom aberration
84-4	Other genotoxic effects
85-1	General metabolism

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